2013-1104
(Serial No. 11/145,716)

In The
United States Court of Appeals
For The Federal Circuit

IN RE KEVIN P. EATON

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD.

CORRECTED JOINT APPENDIX

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/145,716	06/06/2005	Kevin P. Eaton	AZEAT.0001	3770

22858 7590 08/27/2012
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EXAMINER	
SCHLIENTZ, NATHAN W	
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Appendix Page 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEVIN P. EATON

Appeal 2011-013161
Application 11/145,716
Technology Center 1600

Before DEMETRA J. MILLS, LORA M. GREEN, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellant requests rehearing of the Decision on Appeal entered June 20, 2012, which affirmed the rejections of all the pending claims on grounds of anticipation and obviousness.

BACKGROUND

Appellant claims a method of treating psoriasis by administering a vitamin supplement composition "essentially free of anti-oxidants."

The Patent Examiner determined claim 1 anticipated by Jungkeit,[1] claim 11 anticipated by Meredith,[2] claims 1 and 8-10 obvious over Jungkeit and Mantynen,[3] and claims 11 and 14 obvious over Bereston,[4] Plewig,[5] and Mantynen. (Decision 2.) This Board affirmed all the rejections. (*Id.* at 4.)

Appellant requests rehearing of the anticipation rejection of claim 1 over Jungkeit. (Req. Reh'g 4.)

DISCUSSION

According to Appellant, the claim phrase "essentially free of anti-oxidants" must be interpreted as prohibiting vitamin C from the composition used in the claimed method. (*Id.*) The Examiner had found that Jungkeit treated psoriasis with a composition comprising B_6, B_{12}, and folic acid in the requisite amounts. Notwithstanding the fact that Jungkeit's composition also comprised 200μg of vitamin C, we affirmed that Jungkeit anticipated claim 1.

The Decision concluded: "the Examiner correctly interpreted the claim terminology 'essentially free of anti-oxidants' according to the

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[1] Jungkeit, DE 10053155 A1, May 8, 2002.
[2] Meredith, US 7,115,286 B2, issued Oct. 3, 2006.
[3] Mantynen, US 6,107,349, issued Aug. 22, 2000.
[4] Bereston, *Vitamins in Dermatology*, 2 J. CLIN. NUTRI. 133-139 (1954).
[5] Gerd Plewig and Thomas Jansen, Seborrheic Dermatitis 1-17, ch. 126, DERMATOLOGY IN GENERAL MEDICINE, 5th ed. (The McGraw-Hill Companies 1999).

Specification's definition (Ans. 5 and 10-12), and we adopt the Examiner's reasoning." (Decision 3.)

The Specification states:

> By "essentially free" it is meant that the vitamin composition should not contain an amount of antioxidants which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness.

(Spec. 4, ll. 6-10.) The Examiner explained that the 200µg of vitamin C in Jungkeit's B_6, B_{12}, and folic acid composition did not damage or inactivate the B_{12} or folic acid. (Ans. 5.) Because the Specification defined "essentially free" to allow antioxidants as long as they do not damage or inactivate the B_{12} or folic acid, we agreed with the Examiner that claim 1 was reasonably interpreted to allow for 200µg of vitamin C.

The Specification addresses vitamin C as follows:

> In the case of a vitamin supplement compound that is essentially free of antioxidants, among the antioxidants especially to be avoided is added vitamin C, and no antioxidants of any kind should be added to any of the compounds disclosed herein (although such antioxidants may be present during the preparation of such vitamins provided that they are removed afterward, either completely or at least to a level where they have virtually no effect on the vitamin components of the present invention).

(Spec. 6, ll. 1-7.) Like the definition at Spec. 4, quoted above, the guidance at Spec. 6 directs that if vitamin C or other antioxidants are present during preparation of the treatment composition, they should be reduced "at least to a level where they have virtually no effect on the vitamin components of the

present invention." Given this instruction, and the evidence that Jungkeit's composition containing 200μg of vitamin C was effective to treat psoriasis, we continue to agree with the Examiner that claim 1, interpreted in light of the Specification, includes the composition Jungkeit described.

SUMMARY

We have reconsidered the anticipation rejection over Jungkeit as requested, but deny the requested relief.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

DENIED

cdc

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEVIN P. EATON

Appeal 2011-013161
Application 11/145,716
Technology Center 1600

Before DEMETRA J. MILLS, LORA M. GREEN, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) from the rejection of claims directed to a method of treating psoriasis, which the Patent Examiner rejected the claims for anticipation and obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1, 8-11, and 14 are on appeal. Claim 1 is representative and reads:

1. A method of treating psoriasis by administering to a person a vitamin supplement composition comprising at least about 25 micrograms to about 2,200 micrograms of folic acid, at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}, and at least about 0.5 milligrams to about 20 milligrams of vitamin B_6, wherein said composition is essentially free of anti-oxidants.

The Examiner rejected the claims as follows:

- claim 1 under 35 U.S.C. § 102(b) as anticipated by Jungkeit;[1]
- claim 11 under 35 U.S.C. § 102(e) as anticipated by Meredith;[2]
- claims 1 and 8-10 under 35 U.S.C. § 103(a) as obvious over Jungkeit and Mantynen;[3] and
- claims 11 and 14 under 35 U.S.C. § 103(a) as obvious over Bereston, Plewig,[4] and Mantynen.

DISCUSSION

Findings of Fact

1. We adopt the Examiner's findings concerning the scope and content of the prior art. (Ans. 5-12.)

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[1] Erika Jungkeit, DE 10053155 A1, May 8, 2002.
[2] Sarah Meredith, US 7,115,286 B2, effective date July 8, 2003.
[3] Philip R. Mantynen, US 6,107,349, August 22, 2000.
[4] Gerd Plewig et al., Seborrheic Dermatitis 1-17, ch. 126, DERMATOLOGY IN GENERAL MEDICINE, 5th ed. (The McGraw-Hill Companies 1999).

Appellant's Arguments

Appellant contends that the claims are neither anticipated nor obvious because the prior art described compositions that included the antioxidant vitamin C. (App. Br. 9-10.) However, the Examiner correctly interpreted the claim terminology "essentially free of anti-oxidants" according to the Specification's definition (Ans. 5 and 10-12), and we adopt the Examiner's reasoning.

The Examiner found that Jungkeit evidenced that the B vitamins would effectively treat psoriasis even with vitamin C in the composition (Ans. 5), and Appellant criticizes that finding as speculation (App. Br. 10). We conclude the Examiner's reasoning is sound, and find that the Examiner's evidence shifted the burden to Appellant to prove that the Jungkeit or Meredith composition did not work.

> In patent prosecution the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled or whether or not it is the claimed material (as opposed to the unclaimed disclosures) in that patent that are at issue. *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (C.C.P.A.1980) ("[W]hen the PTO cited a disclosure which expressly anticipated the present invention ... the burden was shifted to the applicant. He had to rebut the presumption of the operability of [the prior art patent] by a preponderance of the evidence." (citation omitted)). The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled. *Id.*

Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003). As Appellant's arguments concerning the obviousness rejections rely on the same argument about "essentially free of anti-oxidants," they are unpersuasive for the same reasons.

SUMMARY

We affirm the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Jungkeit.

We affirm the rejection of claim 11 under 35 U.S.C. § 102(e) as anticipated by Meredith.

We affirm the rejection of claims 1 and 8-10 under 35 U.S.C. § 103(a) as obvious over Jungkeit and Mantynen.

We affirm the rejection of claims 11 and 14 under 35 U.S.C. § 103(a) as obvious over Bereston, Plewig, and Mantynen.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

lp

Prosecution History for Patent Application Serial Number 11/145,716

Date	History Text
06/06/2005	Specification, Drawings, Claims, Abstract, Declaration
06/06/2005	Authorization for Extension of Time (all replies)
02/10/2006	Information Disclosure Statement
02/07/2007	Non-Final Rejection
06/07/2007	Response After Non-Final Rejection
02/07/2008	Non-Final Action
08/07/2008	Response After Non-Final Rejection
11/24/2008	Non-Final Rejection
11/24/2008	Examiner Interview Summary
05/26/2009	Response After Non-Final Rejection
08/13/2009	Non-Final Rejection
02/12/2010	Response After Non-Final Rejection
05/21/2010	Final Rejection
10/21/2010	Extension of Time
10/21/2010	Notice of Appeal
03/21/2011	Extension of Time
03/21/2011	Appeal Brief
06/08/2011	Examiner's Answer to Appeal Brief
09/14/2011	Appeal Docketing Notice
06/20/2012	Patent Board Decision – Examiner Affirmed
08/20/2012	Request for Rehearing of Patent Board Decision
08/27/2012	Decision on Reconsideration – Denied
10/26/2012	Appeal to CAFC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Kevin P. EATON
Serial Number:	11/145,716
Filing Date:	June 6, 2005
Confirmation No.:	3770
Art Unit:	1616
Examiner:	Nathan W. SCHLIENTZ
Title:	TREATMENT OF DERMATOLOGICAL CONDITIONS

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CERTIFICATE OF EFS-WEB FILING

Pursuant to 37 CFR. §1.8, I hereby certify that this correspondence is being electronically submitted to the U.S. Patent and Trademark Office website, www.uspto.gov, via EFS Web Filing, on August 20, 2012.

Claudia Alvarado

Claudia S. Alvarado

Dear Sir:

REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.52

Applicants hereby request a Rehearing of the Decision on the Appeal to the Board of Patent Appeals and Interferences (the "Board") issued June 20, 2012 affirming the Examiner's rejection of pending claims 1, 8-11 and 14. The deadline for filing a Request for Rehearing is August 20, 2012, the two-month time period running from the issuance of the Decision on Appeal.

Argument

On page 3, lines 4-6 of the Board's opinion, the Board states that "[T]he Examiner correctly interpreted the claim terminology 'essentially free of anti-oxidants' according to the Specification's definition . . ." The point misapprehended or overlooked was made to the Board in Applicant's Appeal Brief at page 10, lines 2-19. There is no dispute that "essentially free of anti-oxidants" must be interpreted according to the Specification. Even the Examiner admits in his Answer that the Specification states:

> In the case of a vitamin supplement compound that is essentially free of antioxidants, ***among the antioxidants especially to be avoided is added vitamin C, and no antioxidants of any kind should be added to any of the compounds disclosed herein*** . . .

Examiner's June 8, 2011 Answer, page 10 (citing Applicant's Specification page 6, lines 1-4) (emphasis added). It is not reasonable to completely disregard these ***explicit prohibitions*** and interpret "essentially free of anti-oxidants" to mean that Vitamin C can be added to the composition. Yet, Applicant's claims cannot be rejected under 35 U.S.C. § 102(b) unless they are given such an unreasonable interpretation. No reason has been offered to explain why Applicant's explicit instructions in the Specification should be disregarded. Applicant therefore re-urges its position that "essentially free of anti-oxidants" means that no antioxidants of any kind, including Vitamin C, may be added to the claimed compositions.

When Applicant's claims are construed to mean that no antioxidants of any kind, including Vitamin C, may be added, there is no dispute that *Jungkeit* fails to anticipate the claims under § 102(b). This is because everyone recognizes that *Jungkeit* discloses a composition that does include added Vitamin C. For this reason, *Jungkeit* does not anticipate Applicant's claims.

Emphasis has been placed on whether the composition disclosed in *Jungkeit* would work effectively. Respectfully, as noted in Applicant's Appeal Brief (page 10), whether the composition disclosed in *Jungkeit* "works" is irrelevant. The issue is whether the composition of *Jungkeit* includes added Vitamin C. It does, and it is immaterial whether it "works".

CONCLUSION

Applicant has demonstrated that the present invention, as claimed, is clearly distinguishable over the prior art cited by the Examiner. Therefore, Applicant respectfully requests the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection of the pending claims and instruct the Examiner to issue a notice of allowance of all pending claims.

The Commissioner is hereby authorized to charge any fee and credit any overpayment, except the issue fees, to Deposit Account No. 503362.

Respectfully submitted,

KLEMCHUK KUBASTA LLP

Date: August 20, 2012

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Appendix A: Claims on Appeal

Claims

1. (Previously presented) A method of treating psoriasis by administering to a person a vitamin supplement composition comprising at least about 25 micrograms to about 2,200 micrograms of folic acid, at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}, and at least about 0.5 milligrams to about 20 milligrams of vitamin B_6, wherein said composition is essentially free of anti-oxidants.

Claims 2-7 (Canceled).

8. (Previously presented) The method of claim 1 wherein said composition is in the form of a tablet.

9. (Previously presented) The method of claim 1 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

10. (Original) The method of claim 9 wherein said composition is in the form of a tablet.

11. (Previously presented) A method of treating dandruff by administering to a person a vitamin supplement composition consisting essentially of folic acid and vitamin B_{12}, wherein said composition is essentially free of anti-oxidants.

Claims 12-13 (Canceled).

14. (Previously presented) The method of claim 11 wherein said composition contains at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

Claims 15-24 (Canceled).

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subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention is hereby withdrawn.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

DE 10053155 A1	JUNGKEIT	5-2002
7,115,286	MEREDITH	10-2006
6,107,349	MANTYNEN	8-2000
2002/0132800	POPP et al.	9-2002

Bereston, E.S., "Vitamins in Dermatology", The Journal of Clinical Nutrition, vol. 2, no. 2 (March-April 1954), pp. 133-139

Plewig, G. "Seborrheic Dermatitis", FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jungkeit (DE 100 53 155 A1; cited on pg. 2 of the IDS filed 10 February 2006; machine-generated English language translation relied upon herein).

Jungkeit discloses a treatment for psoriasis comprising administration of a multivitamin preparation containing vitamins B_6 at 20 mg, B_{12} at 150 µg and folic acid at 500 µg (Abstract; Table on page 1 of the machine-generated translation; and claim 2).

It is noted that Jungkeit discloses the presence of vitamin C at 200 µg, whereas the instant claims state that the vitamin supplement composition is “essentially free of anti-oxidants". However, the instant claims do not define what amount of antioxidant is within the definition “essentially free of”. The instant specification defines “essentially fee of antioxidants” on page 4, ln. 6-10 as "should not contain an amount of antioxidants which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness". It is not clear from this definition what amount would “damage and inactivate” some of the vitamin B_{12} and/or folic acid. However, it is clear from Jungkeit that the amount of vitamin C present in the composition (200 µg) does not damage and inactivate the vitamin B_{12} and/or folic acid to the extent that the composition is ineffective. Jungkeit discloses that the composition, which comprises 200 µg vitamin C, effectively treats psoriasis.

2. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Meredith (US 7,115,286).

Meredith discloses that sufferers of psoriasis may consider taking extra folic acid (col. 16, ln. 22-23). Meredith also discloses that folic acid is more effective when taken with the B group vitamins, especially vitamins B_{12} and B_6 (col. 16, ln. 34-36). Meredith discloses that the recommended daily allowance (RDA) of folic acid is 400 µg (col. 16, ln. 13), the RDA of vitamin B_{12} is 3 µg (col. 20, ln. 18), and the RDA of vitamin B_6 is 2 mg (col. 19, ln. 2). Meredith also discloses that vitamin B6 may assist in the prevention of dandruff and psoriasis (col. 18, ln. 36-39).

3. Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jungkeit (DE 100 53 155 A1) in view of Mantynen (US 6,107,349).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Jungkeit teaches treating psoriasis with a composition comprising 500 µg folic acid, 150 µg vitamin B_{12}, and 20 mg vitamin B_6.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Jungkeit does not teach treating psoriasis with a composition comprising 800 µg folic acid, 115 µg vitamin B_{12}, and 10 mg vitamin B_6, as instantly claimed. However,

Mantynen teaches treating psoriasis with a composition comprising 800 µg folic acid, 100 µg vitamin B_{12}, and 100 µg vitamin B_6 (Examples 1-3; and claims 5 and 6).

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Jungkeit also does not teach the composition in the form of a tablet. However, one of ordinary skill in the art would readily be able to make the oral composition of Jungkeit into tablets as opposed to capsules.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to adjust the concentrations of folic acid, vitamin B_6 and vitamin B_{12} to arrive an optimum or workable range.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bereston (The Journal of Clinical Nutrition, 1954, 2(2), 133-139) and Popp et al. (US 2002/0132800) in view of Plewig et al. ("Seborrheic Dermatitis", FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17) and Mantynen (US 6,107,349).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Bereston teaches good results in treatment of seborrheic dermatitis with vitamin B_{12} as supplemental therapy (pg. 135, right column, "Other Fractions of Vitamin B Group").

Popp et al. teach that supplementation with folic acid may benefit psoriasis and seborrheic dermatitis patients ([0031]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Bereston and Popp et al. do not teach treatment of dandruff with folic acid and vitamin B_{12}, as instantly claimed. However, Plewig et al. teach that asymptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis (pg. 8 of 17, ln. 13-15).

Bereston and Popp et al. do not teach the amounts of folic acid and vitamin B_{12} to be administered. However, Mantynen teaches that the recommended daily dosage for vitamin B_{12} is 5-200 µg and folic acid is 0.4-1.6 mg (col. 3, ln. 51-57). Thus one of ordinary skill in the art would be able to adjust the amounts of folic acid and vitamin B_{12} for the effective treatment of dandruff.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to treat dandruff (i.e., the mild end of the spectrum of seborrheic dermatitis) with active ingredients taught to treat seborrheic dermatitis. Thus, it would have been *prima facie* obvious to administer folic acid and vitamin B_{12} to treat dandruff because each active ingredient has independently been taught to treat dandruff or seborrheic dermatitis.

Such would have been obvious in the absence of evidence to the contrary because it is generally prima facie obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. The idea of combining them flows

logically from their having been taught individually in the prior art. *In re Kerkhoven* 626 F.2d 646, 850, 205 USPQ 1069, 1072 (CCPA 1980).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

(10) Response to Argument

Appellant argues on pages 9-10 that Jungkeit indisputably discloses a vitamin supplement preparation in which a specified amount of Vitamin C, an antioxidant, is added. Yet, Claim 1 requires that "no antioxidants of any kind should be added", and that Vitamin C is "especially to be avoided". However, the examiner respectfully asserts that claim 1 does not require that no antioxidants of any kind be added. Claim 1 requires that "said composition is *essentially free* of anti-oxidants". The instant specification states,

> By "essentially free" it is meant that the vitamin composition should not contain an amount of antioxidants which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amount of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness.

The specification further states that "among the antioxidants especially to be avoided is added vitamin C, and no antioxidants of any kind should be added to any of the compounds disclosed herein (*although such antioxidants may be present during the preparation of such vitamins provided that they are removed afterward, either*

completely or at least to a level where they have virtually no effect on the vitamin components of the present invention)".

Therefore, the specification states that some antioxidant may be present so long as it has virtually no effect on the vitamin components of the present invention. Also, as noted above, the specification defines “essentially free" as “the vitamin composition should not contain an amount of antioxidants which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness.” Thus, the specification clearly shows that antioxidants can be present in the composition so long as they do not damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement.

Appellant also argues on page 10 that Meredith recommends the use of vitamin C, along with other vitamins. The examiner respectfully argues that Meredith clearly discloses that vitamin B_6 assists in the prevention of dandruff, and that sufferers of psoriasis may consider taking extra folic acid, and folic acid is more effective when taken with the B group vitamins – especially vitamin B12 and vitamin B6. Vitamin C is also recommended. As noted above, the instant specification clearly teaches that antioxidant can be present so long as it does not tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. Thus, Meredith discloses administering vitamin B_6 for the prevention of dandruff and administering folic acid along with vitamin B_6 and B_{12} to patients suffering from psoriasis, and Meredith does not

disclose administering sufficient antioxidant such that the vitamin B_6, vitamin B_{12} and/or folic acid would be damaged or inactivated.

Appellant further argues on page 11 that Jungkeit does not teach "wherein said composition is essentially free of anti-oxidants", and the examiner does not even contend that Bereston, Popp, Surwelack, Plewig and Mantynen teach this limitation. However, the examiner respectfully argues that appellant has not provided any suggestion that Bereston, Popp, Surwelack, Plewig and Mantynen teach the addition of antioxidant. Bereston teach that vitamin B12 is useful for treating seborrheic dermatitis; Popp et al. teach that psoriasis patients are known to be deficient in folic acid and supplementation with folic acid may benefit psoriasis and seborrheic dermatitis patients; Plewig teaches that asymptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis; and Mantynen teaches that the recommended daily dosage for vitamin B_{12} is 5-200 µg and folic acid is 0.4-1.6 mg.

Appellant further argues on page 11 that it stretches credulity to argue that it would have been obvious and apparent for one of ordinary skill in the art to combine no fewer than four references to arrive at the Appellant's claimed invention. However, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Kevin P. EATON
Serial Number:	11/145,716
Filing Date:	June 6, 2005
Confirmation No.:	3770
Art Unit:	1616
Examiner:	Nathan W. SCHLIENTZ
Title:	TREATMENT OF DERMATOLOGICAL CONDITIONS

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF EFS-WEB FILING

Pursuant to 37 CFR. §1.8, I hereby certify that this correspondence is being electronically submitted to the U.S. Patent and Trademark Office website, www.uspto.gov, via EFS Web Filing, on March 21, 2011.

Claudia S. Alvarado

Dear Sir:

APPEAL BRIEF

Applicants hereby Appeal to the Board of Patent Appeals and Interferences (the "Board") from the decision of the Examiner mailed May 21, 2010 finally rejecting pending claims 1,8-11 and 14. Applicants filed a Notice of Appeal on October 21, 2010. The deadline for filing an Appeal Brief is December 21, 2010, the two-month time period running from the filing of the Notice of Appeal.

ATTORNEY DOCKET
1279-0001

APPLICATION
11/145,716

Grounds of Rejection to be Reviewed on Appeal

Applicants request that the Board review the Examiner's rejection of Claim 1 under 35 U.S.C. § 102(b) as being anticipated by German Patent Registration No. DE10053155 A1 to Jungkeit ("*Jungkeit*").

Applicants further request that the Board review the Examiner's rejection of Claim 11 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,115,286 to Meredith ("*Meredith*").

Applicants further request that the Board review the Examiner's rejection of Claims 1 and 8-10 under 35 U.S.C. § 103(a) as being unpatentable over *Jungkeit* in view of US Patent No. 6,107,349 to Mantynen ("*Mantynen*").

Applicants further request that the Board review the Examiner's rejection of Claims 11 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Bereston (The Journal of Clinical Nutrition, 1954, 2(2), 133-139) ("*Bereston*") and U.S. Patent Publication No. 2002/0132800 to Popp, et al. ("*Popp*") in view of Plewig et al. ("Seborrheic Dermatitis," FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17) ("*Plewig*") and *Mantynen*.

Finally, Applicants request that the Board review the Examiner's objection to Claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Argument

Applicants note that the Examiner's decision from which this appeal is taken was the first *final* office action, following four non-final office actions rejecting this application, which was filed on June 6, 2005. In the first office action, the Examiner did not reject any of the Applicants' claims on grounds that they were anticipated by, or obvious in view of, the prior art. *See February 7, 2007 Office Action.* However, the Examiner took the position that the Applicants' claims describe an invention that does not work for its stated purpose, i.e., treatment of psoriasis and dandruff. *See id.* at pp. 2-3. In the second office action, the Examiner withdrew his lack of enablement rejection to the extent the Applicants' claims were directed to a method of treating psoriasis or dandruff, but cited prior art as alleged support for anticipation rejections under 35 U.S.C. § 102 of only *some* of the then pending claims (claims 1 through 6, 11 and 12). *See February 8, 2008 Office Action*, pp. 2, 3, 5-7. In response, Applicants amended the claims so that they were limited in scope to treatment of psoriasis and dandruff using the methods that the Examiner did not reject based on prior art. In his third office action, the Examiner for the first time rejected each of the Applicants' pending claims under Sections 102 and 103, *see November 24, 2008 Office Action*, but one of the "prior art" references cited by the Examiner was not even prior art (i.e., *Hageman*), the word "psoriasis" was not found in the English-language translation of another prior art reference cited by the Examiner (i.e., *Jungkeit*)[1], and the cited portions of the other reference cited by the Examiner merely disclosed the recommended daily allowances for certain vitamins. In the fourth office action, the Examiner finally made the prior art rejections that are included in the final office action, from which this appeal is taken. *See August 13, 2009 Office Action.*

In view of the foregoing history and the below arguments, Applicants respectfully request the Board to reverse the Examiner's rejections and instruct the Examiner to allow all pending claims.

I. Claims 1 And 11 Are Not Anticipated By The Cited Art

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by German Patent Registration No. DE10053155 A1 to Jungkeit (*"Jungkeit"*). *Jungkeit* indisputably discloses a

[1] Subsequently, it became apparent that the Examiner carelessly provided Applicants with an English-language translation of some other non-pertinent reference.

vitamin supplement preparation in which a specified amount of Vitamin C, an antioxidant, is added. The Examiner admits that Claim 1 requires the vitamin supplement composition to be "essentially free of anti-oxidants." Indeed, the Examiner even acknowledges that the specification states:

> In the case of a vitamin supplement compound that is essentially free of antioxidants, among the antioxidants especially to be avoided is added ***Vitamin C***, and no antioxidants of any kind should be added to any of the compounds disclosed herein.

(emphasis added). *Jungkeit* does not anticipate Claim 1.

"[I]n order to demonstrate anticipation, the proponent ***must*** show 'that the four corners of a single, prior art document describe ***every*** element of the claimed invention,'" and that the prior art document "***must*** also disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (emphasis added) (*quoting Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1322 (Fed. Cir. 2006), and *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). *Jungkeit* describes a vitamin supplement preparation in which a specified amount of Vitamin C is added. Yet, Claim 1 requires that "no antioxidants of any kind should be added", and that Vitamin C is "especially to be avoided." The Examiner's speculation that Applicants' invention would work as effectively with added Vitamin C is inappropriate and beside the point. Claim 1 is not anticipated by *Junkgkeit*.

The Examiner's rejection of Claim 11, under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,115,286 to Meredith ("*Meredith*"), is similarly faulty. Like Claim 1, Claim 11 also requires the vitamin supplement composition to be essentially free of antioxidants, meaning that that no antioxidants of any kind should be added and that Vitamin C is especially to be avoided. *Meredith* expressly and affirmatively recommends the use of Vitamin C along with the other vitamins. This fact is dispositive of the Examiner's anticipation rejection based on anticipation. *Meredith* cannot anticipate Claim 11.

As such, Claims 1 and 11 are patentably distinguishable over the references cited by the Examiner.

II. Claims 1, 8-11, and 14 Are Not Obvious In View Of The Cited Art

Claims 1 and 8 through 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jungkeit* in view of US Patent No. 6,107,349 to Mantynen ("*Mantynen*"). As noted above,

Jungkeit does not teach "wherein said composition is essentially free of anti-oxidants," which is a required limitation of each of Claims 1 and 8 through 10. Moreover, the Examiner does not even bother to contend that *Mantynen* teaches this limitation. The Examiner's § 103(a) rejection based on *Jungkeit* in view of *Mantynen*, therefore, is not proper.

Claims 11 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bereston (The Journal of Clinical Nutrition, 1954, 2(2), 133-139) ("*Bereston*") and U.S. Patent Publication No. 2002/0132800 to Popp, et al. ("*Popp*") in view of Plewig et al. ("Seborrheic Dermatitis," FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17) ("*Plewig*") and *Mantynen*. Again, as noted above, *Jungkeit* does not teach "wherein said composition is essentially free of anti-oxidants," which is a required limitation of each of Claims 11 and 14. Moreover, the Examiner again does not even contend that *Bereston*, *Popp*, *Surwelack*, *Plewig*, or *Mantynen* teach this limitation. Finally, it stretches credulity to argue, as the Examiner does, that it would have been obvious and apparent for one of ordinary skill in the art to combine no fewer than four references to arrive at the Applicants' claimed invention.[2] The Examiner's § 103(a) rejection based on these references, therefore, is not proper.

As such, each of Applicants' claims is patentably distinguishable over the references cited by the Examiner.

III. Applicants' Claim 14 Is A Proper Dependent Claim

The Examiner rejects Claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner's rejection is erroneous. "The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) . . ." M.P.E.P. § 608.01(n). Claim 14 clearly and expressly states that it includes all of the limitations of Claim 11: "The method of Claim 11 wherein . . ." Applicants' use of the limitation "[t]he method of Claim 11" necessarily makes Claim 14 "include every limitation of" Claim 11. The Examiner's rejection is, therefore, improper.

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[2] Notably, before the Examiner made this rejection final, he combined ***seven*** references to make up this obviousness rejection. *See August 13, 2009 Office Action*, Page 11.

Request for Relief

Accordingly, Applicants respectfully request that the Board find that all pending claims are allowable.

ATTORNEY DOCKET
1279-0001

APPLICATION
11/145,716

Appendix A: Claims on Appeal

Claims

1. (Previously presented) A method of treating psoriasis by administering to a person a vitamin supplement composition comprising at least about 25 micrograms to about 2,200 micrograms of folic acid, at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}, and at least about 0.5 milligrams to about 20 milligrams of vitamin B_6, wherein said composition is essentially free of anti-oxidants.

Claims 2-7 (Canceled).

8. (Previously presented) The method of claim 1 wherein said composition is in the form of a tablet.

9. (Previously presented) The method of claim 1 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

10. (Original) The method of claim 9 wherein said composition is in the form of a tablet.

11. (Previously presented) A method of treating dandruff by administering to a person a vitamin supplement composition consisting essentially of folic acid and vitamin B_{12}, wherein said composition is essentially free of anti-oxidants.

Claims 12-13 (Canceled).

14. (Previously presented) The method of claim 11 wherein said composition contains at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

Claims 15-24 (Canceled).

REMARKS

Claims 1, 8 through 11, and 14 are pending in the present application. Claim 14 has been amended. Claims 2-7, 12-13, and 15-24 have been cancelled. No claims have been withdrawn. No new claims have been added.

Applicant has carefully studied the outstanding Office Action. The present Response is intended to be fully responsive to all points of objection and rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of this application is respectfully requested in view of the foregoing amendments and following remarks.

Claim Rejections - 35 USC § 112

1. Claims 14 though 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. The Examiner contends that it is improper to use the transitional phrase "comprising" in a claim that depends from an independent claim using the phrase "consisting essentially of". Applicant has canceled Claims 15 through 17, and amended Claim 14 to remove the phrase "comprising". Applicant respectfully requests withdrawal of this § 112, second paragraph rejection in view of Applicant's amendments to the claims.

2. Claims 15 through 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. The Examiner contends that the addition of vitamin B6 to the composition of Claim 11 would materially affect the basic and novel characteristics of the claimed invention. While Applicant does not concede this point, Applicant has canceled Claims

15 through 17, and, therefore, requests withdrawal of the Examiner's rejection of the subject patent application.

Claim Rejections – 35 U.S.C. § 102

1. Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Jungkeit (DE 100 53 155 A1). The Examiner states:

> It is noted that Jungkeit discloses the presence of vitamin C at 200 μg, whereas the instant claims state that the vitamin supplement composition is "essentially free of antioxidants." However, the instant claims do not define what amount of antioxidant is within the definition of "essentially free of". The instant specification defines "essentially free of antioxidants" on page 4, ln. 6-10 as "does not contain an amount [of antioxidants] which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness." It is not clear from this definition what amount would "damage and inactivate" some of the vitamin B_{12} and/or folic acid. However, it is clear from Jungkeit that the amount of vitamin C present in the composition (200 μg) does not damage and inactivate the vitamin B_{12} and/or folic acid to the extent that the composition is ineffective. Jungkeit discloses that the composition, which comprises 200 μg vitamin C, effectively treats psoriasis.

Applicant respectfully requests withdrawal of the Examiner's rejection for reasons including the following: The instant specification further defines the phrase "essentially free of antioxidants" when it states:

> In the case of a vitamin supplement compound that is essentially free of antioxidants, among the antioxidants especially to be avoided is added vitamin C, and no antioxidants of any kind should be added to any of the compounds disclosed herein . . .

Page 6, lines 1-4. Not only does Jungkeit disclose a composition comprising vitamin C, which is "*especially to be avoided*", but Jungkeit discloses that the vitamin C is to be *added* to a "multivitamin preparation". For these reasons, among others, Applicant respectfully requests withdrawal of the Examiner's rejection of Claim 1 based on Jungkeit.

2. Claim 11 is rejected under 35 U.S.C. § 102(e) as being anticipated by Meredith (US 7,115,286). The Examiner actually concedes that Meredith expressly and affirmatively ***recommends*** the use of vitamin C with folic acid and the B group vitamins. This fact is dispositive of a rejection based on Meredith. Since the instant specification further defines the phrase "essentially free of antioxidants" as meaning that added vitamin C should especially be avoided (Page 6, lines 1-4), Meredith does not disclose the "wherein said composition is essentially free of anti-oxidants" limitation of Claim 11. For this reason alone, Applicant respectfully requests withdrawal of the Examiner's rejection of Claim 11 based on Meredith.

Claim Rejections – 35 U.S.C. § 103

1. Claims 1 and 8 through 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jungkeit in view of Mantynen (US 6,107,359). As noted above, Jungkeit does not teach "wherein said composition is essentially free of anti-oxidants," which is a required limitation of each of Claims 1 and 8 through 10. Moreover, the Examiner does not even contend that Mantynen teaches this limitation. The Examiner's § 103(a) rejection based on Jungkeit in view of Mantynen, therefore, is not proper, and Applicant respectfully requests withdrawal of it.

2. Claims 11 and 14 through 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Meredith (US 7,115,286), Bereston (The Journal of Clinical Nutrition, 1954, 2(2), 133-139), Popp et al. (US 2002/0132800), and Suwelack et al. (US 2003/0049325) in view of Plewig et al. ("Seborrheic Dermatitis", FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17), Jungkeit (DE 100 53 155 A1) and Mantynen (US 6,107,349). Claims 15 through 17 have been canceled. Applicant respectfully requests withdrawal of the rejection of Claims 11 and 14. As noted above, neither Jungkeit nor Meredith teach "wherein said composition is essentially free of anti-oxidants," which is a required

limitation of each of Claims 11 and 14. Moreover, the Examiner does not even contend that Bereston, Popp, Suwelack, Plewig, or Mantynen teach this limitation. The Examiner's § 103(a) rejection based on these references, therefore, is not proper, and Applicant respectfully requests withdrawal of it.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/145,716	06/06/2005	Kevin P. Eaton	AZEAT.0001	3770

22858 7590 08/13/2009

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	
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08/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/145,716	EATON, KEVIN P.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-11 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

Claims 1, 8-11 and 14-17 are pending in the present application and are thus examined herein on the merits for patentability. No claim is allowed at this time.

It is noted by the examiner that Applicants did not list claims 18-24 in their "Listing of Claims" submitted 26 May 2009. Each amendment document must include a complete listing of all claims ever presented. The status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), ***(Canceled)***, (Withdrawn), (Previously presented), (New), and (Not entered). Claims 18-24 were canceled in an amendment filed 07 June 2007. Therefore, claims 18-24 are still canceled. Applicants are required in future submissions of "Listing of Claims" to include the status of all claims ever presented, including claims 18-24. See 37 CFR § 1.121(c).

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 11 is drawn to a method of treating dandruff by administering a composition *consisting essentially of* folic acid and vitamin B_{12}. Claims 14-17 use the transitional phrase *comprising* in reference to the composition. By stating *comprising* in claims 14-17, Applicants are broadening the scope of the invention to include any additional ingredients, whereas claim 11 is limited to those ingredients that do not materially affect the basic and novel characteristics of the claimed invention.

Response to Arguments

Applicants argue on page 4 that the compositions of claims 14-17 must also consist essentially of folic acid and vitamin B12 because claims in dependent form shall be construed to include all limitations of the independent claim from with they depend. The examiner acknowledges that claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. However, the recitation of comprising introduces ambiguity into the claims because it is not clear what is included in the scope of the claims because comprising is open-ended.

Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-17 are dependent from claim 11 that uses the transitional phrase "consisting essentially of", which excludes additional ingredients that would materially affect the basic and novel characteristics of the claimed invention. Claim 15 adds vitamin B6 to the composition of claim 11. It is unclear how addition of an active ingredient does not materially affect the basic and novel characteristics of the claimed invention. US 7,115,286 states that folic acid is more effective when combined with vitamin B6 and vitamin B12; and vitamin B6 assists in the prevention of dandruff (col. 16, ln. 34-36; and col. 18, ln. 36-39). Therefore, it appears that addition of vitamin B6 will improve the effectiveness of folic acid, as well as assist in the prevention of dandruff. Thus, addition of vitamin B6 appears to materially affect the basic and novel characteristics of the composition of claim 11.

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's

statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps… [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification… [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jungkeit (DE 100 53 155 A1; cited on pg. 2 of the IDS filed 10 February 2006; machine-generated English language translation relied upon herein).

Jungkeit discloses a treatment for psoriasis comprising administration of a multivitamin preparation containing vitamins B_6 at 20 mg, B_{12} at 150 µg and folic acid at 500 µg (Abstract; Table on page 1 of the machine-generated translation; and claim 2).

It is noted that Jungkeit discloses the presence of vitamin C at 200 µg, whereas the instant claims state that the vitamin supplement composition is “essentially free of antioxidants". However, the instant claims do not define what amount of antioxidant is within the definition “essentially free of”. The instant specification defines “essentially fee of antioxidants” on page 4, ln. 6-10 as "does not contain an amount [of antioxidants] which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced

effectiveness". It is not clear from this definition what amount would "damage and inactivate" some of the vitamin B_{12} and/or folic acid. However, it is clear from Jungkeit that the amount of vitamin C present in the composition (200 µg) does not damage and inactivate the vitamin B_{12} and/or folic acid to the extent that the composition is ineffective. Jungkeit discloses that the composition, which comprises 200 µg vitamin C, effectively treats psoriasis.

Response to Arguments

Applicants argue on page 6 that the translation for Jungkeit does not state the word "psoriasis", therefore the reference cannot provide the basis for a 102(b) rejection. However, the examiner respectfully argues that the translation provided by Applicants clearly shows that Jungkeit discloses the treatment of psoriasis, and the first line of the machine-generated translation clearly states, "Shed lichen (psoriasis) is one of the most frequent skin diseases…" The translation continues to disclose treatment of shed lichen, also known as psoriasis, throughout the document (pg. 1, ln. 1, 8, 12, 14, 15, 40 not counting spaces; and Examples 1-3). Therefore, the machine-generated translation of Jungkeit clearly discloses treatment of psoriasis (shed lichen).

2. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Meredith (US 7,115,286).

Meredith discloses that sufferers of psoriasis may consider taking extra folic acid (col. 16, ln. 22-23). Meredith also discloses that folic acid is more effective when taken with the B group vitamins, especially vitamins B_{12} and B_6 (col. 16, ln. 34-36). Meredith

discloses that the recommended daily allowance (RDA) of folic acid is 400 µg (col. 16, ln. 13), the RDA of vitamin B_{12} is 3 µg (col. 20, ln. 18), and the RDA of vitamin B_6 is 2 mg (col. 19, ln. 2). Meredith also discloses that vitamin B6 may assist in the prevention of dandruff and psoriasis (col. 18, ln. 36-39).

Response to Arguments

Applicants argue on page 7 that Meredith does not disclose "wherein said composition is essentially free of antioxidants". The examiner respectfully argues that Meredith clearly discloses that vitamin B6 assists in the prevention of dandruff, and that sufferers of psoriasis may consider taking extra folic acid, and folic acid is more effective when taken with the B group vitamins – especially vitamin B12 and vitamin B6. Vitamin C is also recommended. The specification defines "essentially free of antioxidants" as "does not contain an amount [of antioxidants] which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness". Thus, Meredith discloses administering vitamin B6 for the prevention of dandruff and administering folic acid along with vitamin B6 and B12 to patients suffering from psoriasis, and Meredith does not disclose administering sufficient antioxidant such that the vitamin B6, vitamin B12 and/or folic acid would be damaged of inactivated.

Applicants further argue on page 7 that Meredith does not teach administering folic acid with vitamins B6 and B12 in the ranges claimed. However, the examiner respectfully argues that claim 11 does not claim amounts of folic acid and vitamin B12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jungkeit (DE 100 53 155 A1) in view of Mantynen (US 6,107,349).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Jungkeit teaches treating psoriasis with a composition comprising 500 µg folic acid, 150 µg vitamin B12, and 20 mg vitamin B6.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Jungkeit does not teach treating psoriasis with a composition comprising 800 µg folic acid, 115 µg vitamin B12, and 10 mg vitamin B6, as instantly claimed. However,

Mantynen teaches treating psoriasis with a composition comprising 800 µg folic acid, 100 µg vitamin B12, and 100 µg vitamin B6 (Examples 1-3; and claims 5 and 6).

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Jungkeit also does not teach the composition in the form of a tablet. However, one of ordinary skill in the art would readily be able to make the oral composition of Jungkeit into tablets as opposed to capsules.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to adjust the concentrations of folic acid, vitamin B6 and vitamin B12 to arrive an optimum or workable range.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meredith (US 7,115,286), Bereston (The Journal of Clinical Nutrition, 1954, 2(2), 133-139), Popp et al. (US 2002/0132800), and Suwelack et al. (US 2003/0049325) in view of Plewig et al. ("Seborrheic Dermatitis", FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17), Jungkeit (DE 100 53 155 A1) and Mantynen (US 6,107,349).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Meredith teaches that pyridoxine (vitamin B6) may assist in the prevention of dandruff, eczema and psoriasis (col. 18, ln. 36-39).

Bereston teaches that seborrheic dermatitis has been treated with oral and parental pyridoxine with variable and unconfirmed results (pg. 135, left column, “Pyridoxine”). Bereston further teaches that good results in seborrheic dermatitis with vitamin B12 as supplemental therapy (pg. 135, right column, “Other Fractions of Vitamin B Group”).

Popp et al. teach that supplementation with folic acid may benefit psoriasis and seborrheic dermatitis patients ([0031]).

Suwelack et al. teach that vitamin B6 deficiency can cause seborrheic dermatitis ([0044]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Meredith, Bereston, Popp et al. and Suwelack et al. do not teach treatment of dandruff with folic acid, vitamin B12 and vitamin B6, as instantly claimed. However, Plewig et al. teach that asymptomatic, fluffy white dandruff of the scalp represents the mild end of the spectrum of seborrheic dermatitis (pg. 8 of 17, ln. 13-15).

Also, Meredith, Bereston, Popp et al. and Suwelack et al. do not teach the B vitamins in the form of tablets, or the exact amounts used for treatment. However, one of ordinary skill in the art would readily be able to formulate the B vitamins as tablets for oral administration. Also, Meredith teaches vitamin B6 as beneficial for treatment and prevention of psoriasis and dandruff; and Popp et al. teach folic acid may be beneficial in psoriasis and seborrheic dermatitis patients. Thus the compositions used to treat psoriasis can also be used to treat dandruff. Jungkeit teaches treating psoriasis with a composition comprising 500 µg folic acid, 150 µg vitamin B12, and 20 mg vitamin B6; and Mantynen teaches treating psoriasis with a composition comprising 800 µg folic acid, 100 µg vitamin B12, and 100 µg vitamin B6 (Examples 1-3; and claims 5 and 6). Thus one of ordinary skill in the art would be able to adjust the amounts of folic acid, vitamin B12 and vitamin B6 for the effective treatment of dandruff.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to treat dandruff (i.e., the mild end of the spectrum of seborrheic dermatitis) with active ingredients taught to treat seborrheic dermatitis. Thus, it would have been *prima facie* obvious to administer folic acid, vitamin B6 and vitamin B12 to treat dandruff because each active ingredient has independently been taught to treat dandruff or seborrheic dermatitis.

Such would have been obvious in the absence of evidence to the contrary because it is generally prima facie obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. *In re Kerkhoven* 626 F.2d 646, 850, 205 USPQ 1069, 1072 (CCPA 1980).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616

Notice of References Cited	Application/Control No. 11/145,716	Applicant(s)/Patent Under Reexamination EATON, KEVIN P.	
	Examiner Nathan W. Schlientz	Art Unit 1616	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2003/0049325	03-2003	Suwelack et al.	424/520
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Eugene S. Bereston, "Vitamins in Dermatology", The Journal of Clinical Nutrition, 1954, 2(2), 133-139.
	V	Gerd Plewig and Thomas Jansen, "Seborrheic Dermatitis", FitzPatrick's Dermatology in General Medicine, 5th Ed., 1999, Ch. 126, pp. 1-11 of 17.
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	Art Unit
	Schlientz, Nathan W	1616

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (history attached)	8/10/09	NWS
Inventor Name Search (PALM and EAST)	8/10/09	NWS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	**Art Unit**
	Nathan W Schlientz	1616

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/26/2007	01/23/2008	11/14/2008	08/06/2009					
	1	✓	✓	✓	✓					
	2	✓	✓	-	-					
	3	✓	✓	-	-					
	4	✓	✓	-	-					
	5	✓	✓	-	-					
	6	✓	✓	-	-					
	7	✓	✓	-	-					
	8	✓	✓	✓	✓					
	9	✓	✓	✓	✓					
	10	✓	✓	✓	✓					
	11	✓	✓	✓	✓					
	12	✓	✓	-	-					
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	17	✓	✓	✓	✓					
	18	O	-	-	-					
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	20	O	-	-	-					
	21	O	-	-	-					
	22	O	-	-	-					
	23	O	-	-	-					
	24	O	-	-	-					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"145716".ap.	US-PGPUB	ADJ	ON	2009/08/10 15:19
L2	7	("20020132800" | "20050256031" | "5932624" | "6265391" | "6605646" | "6900180" | "7115286").PN.	US-PGPUB; USPAT	ADJ	ON	2009/08/10 15:19
L3	462	eaton.in. and kevin.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:19
L4	189	L3 and (folic acid or vitamin B6 or vitamin B12 or psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:19
L5	3218	514/52,251,276,350,356.ccls.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:19
L6	2232	folic acid.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L7	766	vitamin b12.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L8	641	vitamin b6.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L9	283	L6 and L7 and L8	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20

L10	20	L9 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L11	10	L9 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L12	1440	L6 and (vitamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L13	33	L12 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L14	24	L12 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L15	1137	(vitamin b12 or cyanocobalamin or cobalamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L16	1795	(vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L17	2909	(folic acid or folate or pteroyl $glutamic acid or Vitamin B9 or Vitamin M or Folacin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L18	554	L15 and L16 and L17	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20

L19	37	L18 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:20
L20	11	L18 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L21	14578	vitamin b12 or cyanocobalamin or cobalamin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L22	23471	vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L23	30728	folic acid or folate or pteroyl $glutamic acid or Vitamin B9 or Vitamin M or Folacin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L24	5778	L21 and L22 and L23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L25	4996	L21 same L22 same L23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L26	4290	L21 with L22 with L23	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L27	739	L24 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21

L28	413	L25 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L29	362	L26 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L30	70	L24 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L31	67	L25 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:21
L32	58	L26 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L33	59	L26 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L34	2	psoriasis with may benefit with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L35	120	psoriasis with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L36	3433	folic acid with b6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22

L37	8	L35 and L36	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L38	7	dandruff with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L39	9	(dandruff or seborrheic dermatitis) with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L40	20	(dandruff or seborrheic dermatitis) same folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:22
L41	35494	serotonin or melatonin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:27
L42	72500	psoriasis	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:27
L43	129	L41 with L42	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2009/08/10 15:27

EAST Search History (Interference)

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8/10/2009 3:29:17 PM
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PTO 09-7087

CC=DE
DATE=20020508
KIND=A1
PN=10053155

USE OF A MULTIVITAMIN PREPARATION FOR THE TREATMENT OF PSORIASIS [VERWENDUNG EINES MULTIVITAMINPRÄPARATS ZUR BEHANDLUNG DER SCHUPPENFLECHTE]

ERIKA JUNGKEIT

UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. AUGUST 2009
TRANSLATED BY SCHREIBER TRANSLATIONS, INC.

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PRIORITY NUMBER	(31):	
PRIORITY DATE	(32):	
INVENTOR(S)	(72):	ERIKA JUNGKEIT
APPLICANT(S)	(71):	ERIKA JUNGKEIT
DESIGNATED CONTRACTING STATES	(81):	
TITLE	(54):	USE OF A MULTIVITAMIN PREPARATION FOR THE TREATMENT OF PSORIASIS
FOREIGN TITLE	[54A]:	VERWENDUNG EINES MULTIVITAMINPRÄPARATS ZUR BEHANDLUNG DER SCHUPPENFLECHTE

[0001] Psoriasis is one of the most frequent skin diseases, whose genesis, despite numerous theories, has still not been clarified to date. Accordingly, there is also no reliable medicamentous therapy. Medicamentous aid addresses primarily the symptoms of the disease, in order to alleviate the phenomena which appear at the disease foci of the skin, and in particular to reduce the associated pain. Along with the cortisone preparations suited for this, which to be sure also produce undesired side effects, there are numerous agents likewise provided for local treatment, which are produced on the basis of coal tar, urea, salicylic acid, selenium disulfide, finely dispersed sulfur, or the like. There is therefore no medicamentous treatment known with which the impairments of psoriasis can be eliminated sustainably with as few side effects as possible.

[0002] The invention is thus based on the problem of making such a medicamentous treatment possible.

[0003] Proceeding from this problem, in accordance with the invention, the use of a multivitamin preparation containing vitamin B1, vitamin B2, nicotine amide, dexpanthenol, biotin, folic acid, vitamin B6, vitamin B12, vitamin C, and vitamin E is specified for the treatment of psoriasis.

[0004] Quite surprisingly, it has been found that such a multivitamin preparation in the usual dosage and utilized for several months, even after a few weeks, leads to a perceptible remission of

the psoriasis and that after a few months, complete pain-freedom ensues, although the psoriasis at this point is not yet fully healed. Full healing occurs after a significantly longer time.

[0005] The multivitamin preparation comprises multivitamin capsules that are marketed under the name Multibionta forte N of the Merck Company. The utilized capsules contain:

Thiamine-HCl (Vit. B_1)	15 mg
Riboflavin (Vit. B_2)	12.5 mg
Nicotine amide	60 mg
Dexpanthenol	10 mg
Biotin	150 µg
Folic acid	500 µg
Pyridoxine-HCl (Vit. B_6)	20 mg
Cyanocobalamine (Vit. B_{12})	150 µg
Ascorbic acid (Vit. C)	200 mg
DL-Tocopherol acetate	74.5 mg (corresponding to 50 mg of Vit. E)

[0006] Other components of the preparation include:

Partially hardened vegetable oils

Mid-chain triglycerides

Yellow wax

Soy-derived lecithin

Flavoring agent

Gelatin

Glycerin

Anidrisorb

Color iron oxides

[0007] The provided area of application of these capsules is directed toward vitamin deficiency symptoms, which psoriasis is not considered to be. In connection with the treatment of psoriasis or other hyper- or dyskeratosis, at the most high-dose, vitamin A (retinol) (far above the normal daily requirement of an adult of 2 mg) has been discussed as a vitamin active ingredient. The capsules utilized in accordance with the invention do not contain any vitamin A, however, but solely the above vitamin complex. The effectiveness of the multivitamin preparation identified in accordance with the invention is therefore not explainable with the conventional theories.

[0008] The effectiveness of the multivitamin preparation was determined in three randomly selected patients.

Example 1

[0009] A patient, just turned 50 years of age, suffered from an attack of psoriasis on the insides of the hands and fingers to under the nails, as well as on the soles of the feet. The skin was cracked at the affected sites, and the attack was associated with intense pains.

[0010] After years of unsuccessful treatment by various private physicians and at a university clinic, she began to take a

multivitamin preparation (Multibionta forte N-capsules, one capsule per day). After $1^1/_2$ months, the psoriasis receded perceptibly. After about 4 months, pain-freedom set in. The skin was no longer cracked, but was still very sensitive and irritated. About 12 months passed before total healing. Since then, the skin has been delicate and smooth, with no damage whatsoever.

[0011] To be sure, the healing is tied to the further use of the multivitamin capsules. After discontinuation of the multivitamin preparation, the psoriasis breaks out again at the previously affected sites after a few days.

Example 2

[0012] Patient in her early 40s, suffered from an extremely intense attack of psoriasis on both feet. It was impossible to wear normal shoes. The skin was bloody and cracked. About 2 months after the start of using Multibionta forte N capsules (one capsule per day), the patient was pain-free. After around 3 months, she could wear normal shoes again for the first time. The skin is no longer bloody and cracked, and is slowly building back up. The treatment is being continued.

Example 3

[0013] Patient, 32 years old, with an attack of psoriasis on both arms with intensely itchy skin rashes. She was treated with a cortisone cream for the itchiness.

[0014] After around 2 months of taking one capsule of Multibionta forte N a day, the itchiness receded strongly, so that the cortisone cream could be discontinued. The reddening of the affected sites has receded. The treatment is being continued without any other medication.

[0015] The multivitamin preparations of the type used here normally have no side effects, and are suited for a long-term treatment until possible final healing and/or renewed treatment if the symptoms of psoriasis should recur.

/2

Claims

1. Use of a multivitamin preparation containing vitamin B_1, vitamin B_2, nicotine amide, dexpanthenol, biotin, folic acid, vitamin B_6, vitamin B_{12}, vitamin C, and vitamin E for the treatment of psoriasis.

2. Use of a multivitamin preparation in accordance with claim 1 with the following composition:

Vitamin B_1	15 mg
Vitamin B_2	12.5 mg
Nicotine amide	60 mg
Dexpanthenol	10 mg
Biotin	150 µg
Folic acid	500 µg
Vitamin B_6	20 mg

Vitamin B_{12}	150 µg
Vitamin C	200 mg
Vitamin E	50 mg.

3. Use of a multivitamin preparation in accordance with claim 1 or 2, which contains no vitamin A or vitamin A ≤ 2 mg.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/145,716	06/06/2005	Kevin P. Eaton	AZEAT.0001	3770

22858 7590 11/24/2008

CARSTENS & CAHOON, LLP
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EXAMINER	
SCHLIENTZ, NATHAN W	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/145,716	EATON, KEVIN P.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-11 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-11 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Interview Summary	Application No.	Applicant(s)	
	11/145,716	EATON, KEVIN P.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Nathan W. Schlientz*. (3)_____.

(2) *Casey L. Griffith*. (4)_____.

Date of Interview: *18 November 2008*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *all pending*.

Identification of prior art discussed: *DE 10053155, US 2005/0256031, US 7,115,286*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Nathan W Schlientz/ Examiner, Art Unit 1616	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Attorney Griffith and the examiner discussed the merits of the case. Attorney Griffith discussed that claims 7-10 and 13-17 were not rejected under 35 USC 102 or 103 in the office action mailed 07 February 2008, and the amendment to the claims filed 07 August 2008 attempted to incorporate the subject matter of these claims into the currently pending claims (claims 1, 8-11 and 14-17). Attorney Griffith also commented that the claim amendments attempted to overcome the scope of enablement rejection. The examiner agrees that the 112 rejection, scope of enablement rejection, has been overcome by the claim amendments. However, upon further consideration, the examiner feels the currently pending claims are not novel or non-obvious, especially in view of DE 100 53 155, US 2005/0256031, and US 7,115,286. The examiner will send an office action detailing the rejections of the claims.

.

DETAILED ACTION

Status of the Claims

Claims 2-7, 12 and 13 were cancelled in an amendment filed 07 August 2008. As a result, claims 1, 8-11 and 14-17 are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 11 is drawn to a method of treating dandruff by administering a composition *consisting essentially of* folic acid and vitamin B_{12}. Claims 14-17 use the transitional phrase *comprising* in reference to the composition. By stating *comprising* in claims 14-17, Applicants are broadening the

scope of the invention to include any additional ingredients, whereas claim 11 is limited to those ingredients that do not materially affect the basic and novel characteristics of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jungkeit (DE 100 53 155 A1; cited on pg. 2 of the IDS filed 10 February 2006; machine-generated English language translation relied upon herein, and a copy attached).

Jungkeit discloses a treatment for psoriasis comprising administration of a multivitamin preparation containing vitamins B_6 at 20 mg, B_{12} at 150 µg and folic acid at 500 µg (Abstract; Table on page 1 of the machine-generated translation; and claim 2).

It is noted that Jungkeit discloses the presence of vitamin C at 200 µg, whereas the instant claims state that the vitamin supplement composition is “essentially free of antioxidants". However, the instant claims do not define what amount of antioxidant is within the definition “essentially free of”. The instant specification defines “essentially

fee of antioxidants" on page 4, ln. 6-10 as "does not contain an amount [of antioxidants] which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness". It is not clear from this definition what amount would "damage and inactivate" some of the vitamin B_{12} and/or folic acid. However, it is clear from Jungkeit that the amount of vitamin C present in the composition (200 µg) does not damage and inactivate the vitamin B_{12} and/or folic acid to the extent that the composition is ineffective. Jungkeit discloses that the composition, which comprises 200 µg vitamin C, effectively treats psoriasis.

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Hageman et al. (US 2005/0256031).

Hageman et al. disclose treating persons who have or are at risk of developing psoriasis with a composition comprising 600-6000 µg folic acid, 6-540 µg vitamin B_{12}, and 3.4-30 mg vitamin B_6 per daily dose ([0035] and claim 19).

3. Claims 1, 11, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Meredith (US 7,115,286).

Meredith discloses that suffers of psoriasis may consider taking extra folic acid (col. 16, ln. 22-23). Meredith also discloses that folic acid is more effective when taken with the B group vitamins, especially vitamins B_{12} and B_6 (col. 16, ln. 34-36). Meredith

discloses that the recommended daily allowance (RDA) of folic acid is 400 µg (col. 16, ln. 13), the RDA of vitamin B_{12} is 3 µg (col. 20, ln. 18), and the RDA of vitamin B_6 is 2 mg (col. 19, ln. 2). Meredith also discloses that vitamin B6 may assist in the prevention of dandruff and psoriasis (col. 18, ln. 36-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hageman et al. (US 2005/0256031).

Applicant's claims

Applicants claim a method of treating psoriasis by administering to a person a composition comprising 25-2,200 µg folic acid, 25-2,500 µg vitamin B_{12}, and 0.5-20 mg vitamin B_6, wherein said composition is essentially free of antioxidants, and is in the

form of a tablet. Applicant's further claim the method of claim 1 wherein the composition comprises 800 µg folic acid, 115 µg vitamin B_{12}, and 10 mg vitamin B_6.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Hageman et al. teach treating persons who are at risk of developing or already have psoriasis by administering a composition comprising 600-6000 µg folic acid, 6-540 µg vitamin B_{12}, and 3.4-30 mg vitamin B_6 per daily dose ([0035] and claim 19).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Hageman et al. do not explicitly teach a composition in the form of a tablet. However, Hageman et al. teach that the product can be in the form of a liquid or powder, in the form of a meal, or other suitable forms that are known to a person skilled in the art. It is well within the purview of one skilled in the art to form a tablet from the powdered product.

Hageman et al. also do not explicitly teach a composition comprising 800 µg folic acid, 115 µg vitamin B_{12}, and 10 mg vitamin B_6. However, the amounts taught by Hageman et al., 600-6000 µg folic acid, 6-540 µg vitamin B_{12}, and 3.4-30 mg vitamin B_6 per daily dose, encompass the instantly claimed amounts of each component. It would have been well within the purview of one skilled in the art to determine the optimum or workable amounts of each ingredient.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to formulate the composition of Hageman et al. into tablet form, as well as determine the optimum or workable amounts of each component.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

2. Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hageman et al. (US 2005/0256031) in view of Meredith (US 7,115,286) and Sauermann et al. (EP 0 747 035; English language abstract and English language machine-generated translation referred to herein).

Applicant's claims

Applicants claim a method of treating dandruff by administering to a person a composition comprising 25-2,200 µg folic acid, 25-2,500 µg vitamin B_{12}, and 0.5-20 mg vitamin B_6, wherein said composition is essentially free of antioxidants, and is in the form of a tablet. Applicant's further claim the method of claim 1 wherein the composition comprises 800 µg folic acid, 115 µg vitamin B_{12}, and 10 mg vitamin B_6.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Hageman et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Hageman et al. do not teach treating dandruff with their composition, which comprises folic acid, vitamin B_6 and vitamin B_{12} within the instantly claimed ranges. However, Meredith teaches that vitamin B_6 assists in the prevention of dandruff, eczema, and psoriasis (col. 18, ln. 36-39). Also, Sauermann et al. teach that folic acid is beneficial in the prevention and treatment of dandruff (Abstract).

Hageman et al. also do not explicitly teach a composition in the form of a tablet. However, Hageman et al. teach that the product can be in the form of a liquid or powder, in the form of a meal, or other suitable forms that are known to a person skilled in the art. It is well within the purview of one skilled in the art to form a tablet from the powdered product.

Hageman et al. also do not explicitly teach a composition comprising 800 µg folic acid, 115 µg vitamin B_{12}, and 10 mg vitamin B_6. However, the amounts taught by Hageman et al., 600-6000 µg folic acid, 6-540 µg vitamin B_{12}, and 3.4-30 mg vitamin B_6 per daily dose, encompass the instantly claimed amounts of each component. It would have been well within the purview of one skilled in the art to determine the optimum or workable amounts of each ingredient.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer the composition of Hageman et al., which comprises folic acid, vitamin B_6 and vitamin B_{12}, for the treatment of dandruff. One of ordinary skill in the art would have been motivated to use the composition of Hageman et al. to treat dandruff because Meredith teaches that vitamin B_6 assists in the prevention of dandruff, and Sauermann et al. teach that folic acid is beneficial in the prevention and treatment of dandruff.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616

Notice of References Cited	Application/Control No. 11/145,716	Applicant(s)/Patent Under Reexamination EATON, KEVIN P.	
	Examiner Nathan W. Schlientz	Art Unit 1616	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0256031	11-2005	Hageman et al.	514/002
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	EP 747035 A2	12-1996	European Patent	SAUERMANN et al.	A61K 007/06
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	Art Unit
	Schlientz, Nathan W	1616

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/26/2007	01/23/2008	11/14/2008						
	1	✓	✓	✓						
	2	✓	✓	-						
	3	✓	✓	-						
	4	✓	✓	-						
	5	✓	✓	-						
	6	✓	✓	-						
	7	✓	✓	-						
	8	✓	✓	✓						
	9	✓	✓	✓						
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	11	✓	✓	✓						
	12	✓	✓	-						
	13	✓	✓	-						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	✓	✓	✓						
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	21	O	-	-						
	22	O	-	-						
	23	O	-	-						
	24	O	-	-						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	Art Unit
	Schlientz, Nathan W	1616

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (history attached)	11/14/08	NWS
Inventor Name Search (PALM and EAST)	11/14/08	NWS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"145716".ap.	US-PGPUB	ADJ	ON	2008/11/20 14:47
L2	7	("20020132800" | "20050256031" | "5932624" | "6265391" | "6605646" | "6900180" | "7115286").PN.	US-PGPUB; USPAT	ADJ	ON	2008/11/20 14:48
L3	456	eaton.in. and kevin.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:48
L4	188	L3 and (folic acid or vitamin B6 or vitamin B12 or psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:48
L5	3086	514/52,251,276,350,356.ccls.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:48
L11	2086	folic acid.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L12	701	vitamin b12.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L13	600	vitamin b6.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L14	263	L11 and L12 and L13	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49

L15	19	L14 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L16	10	L14 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L17	1354	L11 and (vitamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L18	31	L17 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L19	24	L17 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L20	1056	(vitamin b12 or cyanocobalamin or cobalamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L21	1682	(vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L22	2700	(folic acid or folate or pteroyl $glutamic acid or Vitamin B9 or Vitamin M or Folacin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L23	523	L20 and L21 and L22	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49

L24	35	L23 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L25	11	L23 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L26	12808	vitamin b12 or cyanocobalamin or cobalamin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L27	21052	vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L28	27218	folic acid or folate or pteroyl $glutamic acid or Vitamin B9 or Vitamin M or Folacin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L29	4663	L26 and L27 and L28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:49
L30	3933	L26 same L27 same L28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L31	3252	L26 with L27 with L28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L32	681	L29 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50

L33	370	L30 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L34	324	L31 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L35	61	L29 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L36	58	L30 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L37	51	L31 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L38	52	L31 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L39	2	psoriasis with may benefit with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L40	107	psoriasis with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L41	2485	folic acid with b6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50

L42	8	L40 and L41	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L43	6	dandruff with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L44	8	(dandruff or seborrheic dermatitis) with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:50
L45	18	(dandruff or seborrheic dermatitis) same folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/11/20 14:51

11/20/2008 3:39:05 PM
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DERWENT-ACC-NO: 1997-035912

DERWENT-WEEK: 199704

TITLE: Use of one or more basic aminoacid cpds. and opt. folic acid in hair treatments esp. arginine, ornithine, citrulline or lysine, useful in treatment of dandruff as a topical compsn.

INVENTOR: RIEDEL J; SAUERMANN G ; SCHMIDT-LEWERKUEHNE H

PRIORITY-DATA: 1995DE-1020662 (June 7, 1995)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE
EP 747035 A2	December 11, 1996	DE
DE 19520662 A1	December 12, 1996	DE

INT-CL-CURRENT:

TYPE	IPC	DATE
CIPS	A61K8/44	20060101
CIPS	A61K8/67	20060101
CIPS	A61Q5/00	20060101
CIPS	A61Q5/12	20060101

ABSTRACTED-PUB-NO: EP 747035 A2

BASIC-ABSTRACT:

Use of one or more basic amino-acids selected from arginine, ornithine, citrulline or lysine or their salts, acid addition salts, esters or amides with opt. addn. of folic acid or its salt for prevention and treatment of dandruff and improving hair condition.

---------- KWIC ---------

Basic Abstract Text - ABTX (1):

Use of one or more basic amino-acids selected from arginine, ornithine,
citrulline or lysine or their salts, acid addition salts, esters or amides with
opt. addn. of folic acid or its salt for prevention and treatment of dandruff
and improving hair condition.

Title - TIX (1):

Use of one or more basic aminoacid cpds. and opt. folic acid in hair
treatments esp. arginine, ornithine, citrulline or lysine, useful in treatment
of dandruff as a topical compsn.

Standard Title Terms - TTX (1):

ONE MORE BASIC AMINOACID COMPOUND OPTION FOLIC ACID HAIR TREAT ARGININE
ORNITHINE CITRULLINE LYSINE USEFUL DANDRUFF TOPICAL COMPOSITION

Result Page

Agent to the treatment of head sheds and to the treatment of the hairs.

The invention relates to in particular active ingredients and cosmetic and dermatological preparing, in particular topical preparing, to the prophylaxis and treatment of head sheds and the hairs.

Agents to the treatment of flakes and to the improvement of the hair firmness are known. Their effect is however not always satisfactory.

Object of the invention is it to create active ingredients and agents for the prophylactic fight against head sheds and to the treatment of head sheds and to the improvement of the hair firmness the disadvantages of the state of the art avoids.

These objects become dissolved by the use of basic amino acid, in particular or several compounds, selected from the group of arginine, ornithine, Citrullin and lysine or their salts, acid addition salts, esters, or amides, if necessary bottom addition of folic acid or their salts, to the prophylaxis and treatment of head sheds and the improvement of the hair firmness.

Subject-matter of the invention are also cosmetic and dermatological preparing, in particular hair-cosmetic preparing and hair care products, which contain the active ingredients according to invention, and whose use to the prophylaxis and treatment of head sheds and to the improvement of the hair firmness.

Prefered ones become L arginine, L-ornithine, L-Citrullin and L lysine.

Topical preparing become prefered.

Prefered salts of the amino acids, in particular of arginine, ornithine, lysine and Citrullin are water-soluble salts, e.g. Sodium, potassium and ammonium salts. This applies also to the acid addition salts. Suitable acid addition salts become obtained with inorganic and organic acidic ones. Prefered ones become the hydrochlorides, sulfates, acetates, Caprylate or Zitrate.

Suitable esters of these compounds e.g. are. such, which become formed with kurzkettigen and mittelkettigen alcohols, preferably mono alcohols, in particular however methanol, ethanol or propanol. Prefered ones become the ethyl esters.

Prefered amides are short and mittelkettige mono and dialkyl amides.

Alkyls of the managing substituents e.g. contain. up to 12, preferably up to 6 carbon atoms.

Particularly prefered becomes arginine and active substance combinations and topical preparing, which contain arginine and/or its derivatives according to invention.

L arginine and its derivatives is characterised also by a particularly good penetration ability.

The basic amino acid according to invention, e.g. Arginine, Citrullin, ornithine and lysine and/or their derivatives preferably are in amounts from 0,01 to 30 Gew. - %. particularly prefered 0.01 to 10 Gew. - %, in particular 0.1 - 7.5 Gew. - %, in each case related to the entire preparation, into which cosmetic and dermatological preparing according to invention contain. The active ingredients and their derivatives can become single or in combination used. Preparing however preferably contain arginine, of particularly prefered L arginine, in amounts from 0,01 to 10 Gew. - %, related to the entire preparation.

Prefered ones become also combinations or the several basic amino acid with folic acid.

Particularly suitable salts of the folic acid are water-soluble salts, in particular sodium, potassium and ammonium salts.

Folic acid or their salts is preferably contained of prefered in the preparing according to invention, in each case in amounts from 0,001 to 5 Gew. - %, in particular 0.01 to 1.5 Gew. - %, in each case related to the total weight of the preparing.

The cosmetic or dermatological topical preparing according to invention can be based to daily at the scalp or the hairs applied on actual conventional formulation bases and for the treatment of the scalp and the hairs in the sense of a dermatological treatment or a treatment in the sense of the maintaining Kosmetik serve and become in actual known manner once or several times.

Dermatological and cosmetic preparing according to the invention can be present in actual known forms. So can e.g. aqueous, alcoholic or aqueous-alcoholic solutions, emulsions of the type oil in water (O/W), emulsions of the type water in oil (W/O), multiple emulsions e.g. of the type water in oil in water (W/O/W), gels, hydraulic dispersions, fixed pins or aerosols the above mentioned. Active substance combinations or active ingredients contain.

Prefered preparing are topical hair-cosmetic preparing and to the use at the scalp of suitable and conventional agents.

Suitable hair treatment means are in particular shampoo, hair preservative agent, hair conditioning means, hair cure, hair flushing, Haarfestiger, hair deformation means, coloring means, hue means and bleaching agent.

▲ top

The preparing according to the invention can be present in various form, in particular as solutions, gel, cream, oil, emulsion or every different one to the striking and hair treatment of suitable form. They can be also as aerosol in presence of a propellant conditioned.

For this, in particular also for hair treatment means, numerous cosmetic acceptable ingredients can become used. The preparing can contain in particular: anionic, cationic, nonionic, amphoteric surface-active agents and their mixtures. The bottom surface-active agents are to be called: Alkylbenzenesulfonates, Alkylnaphthalinsulfonate, sulfates, Ethersulfate and Fettalkoholsulfonate, quaternary ammonium salts, Fettsäurediethanolamide, and polyglycerinierte acidic one and alcohols polyoxyethylierte, polyoxyethylierte and polyglycerinierte Alklyphenole, as well as polyoxyethylierte alkyl sulfates. The surface-active products e.g. lie in the preparing according to the invention. in portions between 0,5 and 55 Gew. - %, preferably between 4 and 40 Gew. - %, related to the total weight of the preparation forwards.

The preparing can contain waters and also organic solvents, in order solubilisieren the compounds to, which are not in waters in sufficient mass soluble. The bottom solvents can e.g. mentioned become: Low alkane oils, like ethanol and isopropanol, glycerol, glycols or Glykolether, like Butoxy-2-ethanol, ethylene glycol, propylene glycol, Diethylenglykolmonoethyl and more monomethylether, as well as analogue products and their mixtures. These solvents preferably lie in portions from 1 to 40 Gew. - %, in particular from 5 to 30 Gew. - %, related to the total weight of the preparing forwards.

The preparing can preferably with common salt or with compounds from the group sodium alginate, Gummiarabicum, cellulose derivatives, like methyl cellulose, hydroxyethyl cellulose, Hydroxypropylethylcellulose, carboxymethyl cellulose and various polymers, which possess these properties, as in particular acrylic acid derivatives become, thickened. It is also possible to use inorganic thickeners like e.g. Bentonite. These thickeners preferably lie in portions between 0,05 and 5 Gew. - %, prefered between 0,5 and 3 Gew. - %, related to the total weight of the preparing forwards.

It is natural possible to admit to the preparing according to the invention any other ingredients how they become ordinary used, in particular Penetrationsagentien, Sequestrierungsagentien, film-formed agents, buffers and Parfüme.

Finally still other conventional cosmetic additions, for example such as Ascorbiensäure or sodium sulfite, know Antioxidantien alkalization means such as alkali hydroxides, ammonium and/or in the preparing. Alkali carbonate and ammonium and/or. Alkali hydrogencarbonate, organic acidic ones like e.g. Acetic acid, lactic acid and citric acid, solvent, perfume, swelling agent, wetting agent, emulsifiers, care materials and other present its.

Depending upon composition the preparing according to invention weak acidic, neutral or alkaline can react.

The topical preparing according to invention, which serve the scalp in particular also for the treatment, can contain cosmetic adjuvants, become like them usually in such preparing used, e.g. Preservative, bactericidal one, Parfüme, agent for preventing the sudsy, dyes, pigments, which have a coloring effect, thickeners, surface-active substances, emulsifiers, softening substances, dampening and/or feuchhaltende substances, fats, oils, wax or other conventional ingredients of a cosmetic formulation such as alcohols, polyols, polymers, foam stabilisers, electrolytes, organic solvents or silicone derivatives.

If the cosmetic or dermatological preparation represents a solution or a lotion, used can become as solvents:

Water or aqueous solutions;
Oils, like triglycerides of the Caprin or the caprylic acid, preferably however castor oils;
Fats, wax and other natural and synthetic fat bodies, preferably esters of fatty acids with alcohols low C-number, e.g. with isopropanol, propylene glycol or glycerol, or ester of fatty alcohols with alkanoic acids low C-number or with fatty acids;
Alcohols, diols or polyols low C-number, as well as their ether, preferably ethanol, isopropanol, propylene glycol, glycerol, ethylene glycol, ethyl glycol mono ethyl or - more monobutylether, propylene glycol mono methyl, - mono ethyl or - more monobutylelher, Diethylenglykolmonomethyl or - more monoethylether and analogue products.

In particular mixtures become that solvents managing specified used. With alcoholic solvents water can be an other ingredient.

Cosmetic and dermatological preparing for the treatment and care of the skin can be present as gels, those beside the active ingredients and but usually used solvents still organic thickeners, e.g. Gum Arabic, xanthan gum, sodium alginate, cellulose derivatives, preferably methyl cellulose, Hydroxymethylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethylcellulose or inorganic thickeners, z. B. Aluminium silicates as for example bentonites, or a mixture from polyethylene glycol and Polyethylenglykolstearat or - contain distearat. The thickener e.g. is in the gel. in an amount between 0,1 and 30 Gew. - %, prefered between 0,5 and 15 Gew. - %, contain.

Gels according to invention contain usually alcohols of low C-number, e.g. Ethanol, isopropanol, 1,2-Propandiol, glycerol and water and/or. an oil managing specified in presence of a thickener, which is preferably with oily-alcoholic gels silica or an aluminium silicate, with aqueous-alcoholic or alcoholic gels a vorzugweise polyacrylate.

Hydraulic dispersions represent dispersions of a liquid, semisolid or solid inner (discontinuous) lipid phase in an outside aqueous (continuous) phase.

In contrasts to O/W emulsions, which are characterised by a similar phase arrangement, are hydraulic dispersions however essentially free of emulsifiers. Hydraulic dispersions represent, like in all other respects also emulsions, metastable systems and are inclined to change over into a state of two discrete phases contiguous in itself. In emulsions the prevented choice of a suitable emulsifier the phase separation.

With hydraulic dispersions of a liquid lipid phase in an outside aqueous phase those can become the stability of such a system for example thereby ensured that in the aqueous phase a gel stand becomes constructed, in which the Lipidtröpfchen stable suspended is.

Fixed pins according to the invention can e.g. natural or synthetic wax, fatty alcohols or fatty acid esters contain.

When propellants for cosmetic or dermatological preparing according to invention sprayable from aerosol containers are the conventional known volatile, liquefied propellants, for example hydrocarbons (propane, butane, isobutane) suitable, which alone or in mixture used with one another to become to be able. Also compressed air is to be used

favourably.

The according to invention, e.g. topical preparing, can contain the conventional adjuvants, emulsifiers and preservatives.

The active ingredients according to invention, active substance combinations and the preparing, which contain it, possess a pronounced anti shed effect. They are to the treatment of the head sheds and suitable to the prophylactic treatment of the Schuppenbildung of the scalp and their flakyness. Further they increase the strength of the hairs. They serve the Vorbeugung and treatment of gesplissenem hair (Spliss) or broken hair or in other manner damaged hair, in particular the Kopfhaar.

Subject-matter of the invention is also the method to the preparation of the according to invention, z. B. topical preparing, which is characterized by the fact that one trains the active ingredients in actual known manner in cosmetic or dermatological formulations.

All quantity specifications, portions and percentage shares are, so far not different indicated, on the weight and the total amount and/or. on the total weight of the preparing based.

The subsequent examples are to clarify the present invention, without limiting it.

Example 1

<tb>< TABLE> Columns=2
<tb>
<tb> Head Col 1: Shampoo (CTFA)
<tb> Head Col 2: Gew. - %
<tb> Natriumlaurylethersulfat (2 EO, 20%)< September> 40
<tb> Lauryl dimethylamino acetic acid betaines (30%)< September> 4
<tb> Cocamide DEA, Coconut fatty acid diethanolamine< September> 1.5
<tb> Oleth-3 of phosphates, Oleyl triethoxy phosphates, (Briphos O3D, Albright & Wilson)< September> 1
<tb> PEG-15 cocopolyamine, Polyglycol polyamine condensation resin (Polyquart H, Henkel, 50%)< September> 2
<tb> L-Argininhydrochlorid< September> 5
<tb> water, VES (demineralized)< September> ad 100
<tb>< /TABLE>

Example 1 A

It will proceed as in example 1, and 0.5 Gew become. - % folic acid added.

Example 2

<tb>< TABLE> Columns=2
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<tb> Head Col 1: Hydraulic dispersion
<tb> Head Col 2: Gew. - %
<tb> L-Ornithinhydrochlorid< September> 1,0
<tb> Phenyltrimethicon< September> 1,0
<tb> Carbomer (Carbopol 981)< September> 1,0
<tb> hydroxypropylmethylcellulose< September> 0,2
<tb> butylene glycols< September> 3,0
<tb> Tromethamin< September> q.s.
<tb> NaOH solution (15-Gew. - %ig)< September> q.s.
<tb> ethanol< September> 5,0
<tb> perfume, preservative< September> q.s.
<tb> water, VES< September> ad 100,0
<tb>< /TABLE>

Example 2 A

At site of L-Ornithinhydrochlorid the same amount by weight becomes L-Argininhydrochlorid added.

Example 3

<tb>< TABLE> Columns=2
<tb>
<tb> Head Col 1: Lotion W/O
<tb> Head Col 2: Gew. - %
<tb> L-Argininhydrochlorid< September> 0,5
<tb> folic acid< September> 0,1
<tb> Cyclomethicon< September> 3,0
<tb> PEG-1-Glycerin sorbitan Oleostearat< September> 1,7
<tb> PEG-7 hydrogenated castor oil< September> 6,3
<tb> mineral oil (DAB 9)< September> 13,9
<tb> Caprylic/capric of triglycerides< September> 13,0
<tb> magnesium sulfate< September> 0,7
<tb> perfume, preservative< September> q.s.
<tb> water, VES< September> ad 100
<tb>< /TABLE>

Example 4

<tb>< TABLE> Columns=2
<tb>
<tb> Head Col 1: Haarwasser (Tonikum)
<tb> Head Col 2: Gew. - %
<tb> L arginine< September> 0,5
<tb> ethanol< September> 50

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<tb> waters< September> ad 100
<tb>< /TABLE>

Example 4 A

It will proceed as in example 4 indicated, and additional 0.5 Gew become. - % folic acid added.

Example 5

<tb

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Claims of EP0747035	Print	Copy	Contact Us	Close

Result Page

1. Use of basic amino acid, in particular or several compounds, selected from the group of arginine, ornithine, Citrullin and lysine or their salts, acid addition salts, esters or amides, if necessary bottom addition of folic acid or their salts, to the prophylaxis and treatment of head sheds and to the improvement of the hair firmness.

2. Cosmetic and dermatological preparing, in particular hair-cosmetic preparing and hair care products, which contain the active ingredients according to invention of according to claim 1, and whose use to the prophylaxis and treatment of head sheds and to the improvement of the hair firmness.

3. Active ingredients and preparing according to claim 1 or 2, characterised in that the active ingredients L arginine, L-ornithine, L-Citrullin and/or L lysine and/or their derivatives and/or. Salts are.

4. Active ingredients and preparing in accordance with the managing claims, characterized by content on or addition of folic acid and/or their salts.

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(11) EP 0 747 035 A2

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(54) Mittel zur Behandlung von Kopfschuppen und zur Behandlung der Haare

(57) Gegenstand der Erfindung ist die Verwendung von basischen Aminosäuren, insbesondere einer oder mehrerer Verbindungen, ausgewählt aus der Gruppe von Arginin, Ornithin, Citrullin und Lysin oder deren Salzen, Säureadditionssalzen, Estern oder Amiden, gegebenenfalls unter Zusatz von Folsäure oder deren Salzen, zur Prophylaxe und Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit.

EP 0 747 035 A2

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Beschreibung

Mittel zur Behandlung von Kopfschuppen und zur Behandlung der Haare.

Die Erfindung betrifft insbesondere Wirkstoffe und kosmetische und dermatologische Zubereitungen, insbesondere topische Zubereitungen, zur Prophylaxe und Behandlung von Kopfschuppen und der Haare.

Mittel zur Behandlung von Schuppen und zur Verbesserung der Haarfestigkeit sind bekannt. Ihre Wirkung ist aber nicht immer befriedigend.

Aufgabe der Erfindung ist es, Wirkstoffe und Mittel zur prophylaktischen Bekämpfung von Kopfschuppen und zur Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit zu schaffen, die Nachteile des Standes der Technik vermeiden.

Diese Aufgaben werden gelöst durch die Verwendung von basischen Aminosäuren, insbesondere einer oder mehreren Verbindungen, ausgewählt aus der Gruppe von Arginin, Ornithin, Citrullin und Lysin oder deren Salzen, Säureadditionssalzen, Estern, oder Amiden, gegebenenfalls unter Zusatz von Folsäure oder deren Salzen, zur Prophylaxe und Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit.

Gegenstand der Erfindung sind auch kosmetische und dermatologische Zubereitungen, insbesondere haarkosmetische Zubereitungen und Haarpflegeprodukte, welche die erfindungsgemäßen Wirkstoffe enthalten, und deren Verwendung zur Prophylaxe und Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit.

Bevorzugt werden L-Arginin, L-Ornithin, L-Citrullin und L-Lysin.

Topische Zubereitungen werden bevorzugt.

Bevorzugte Salze der Aminosäuren, insbesondere von Arginin, Ornithin, Lysin und Citrullin sind wasserlösliche Salze, z.B. Natrium-,Kalium- und Ammoniumsalze. Dies gilt auch für die Säureadditionssalze. Geeignete Säureadditionssalze werden mit anorganischen und organischen Säuren erhalten. Bevorzugt werden die Hydrochloride, Sulfate, Acetate, Caprylate oder Zitrate.

Geeignete Ester dieser Verbindungen sind z.B. solche, die mit kurzkettigen und mittelkettigen Alkoholen gebildet werden, vorzugsweise mono-Alkoholen, insbesondere aber Methanol, Ethanol oder Propanol. Bevorzugt werden die Ethylester.

Bevorzugte Amide sind kurz- und mittelkettige mono- und di-Alkylamide.

Alkyle der vorstehenden Substituenten enthalten z.B. bis zu 12, vorzugsweise bis zu 6 Kohlenstoffatome.

Besonders bevorzugt werden Arginin und Wirkstoffkombinationen und topische Zubereitungen, die Arginin und/oder dessen erfindungsgemäße Derivate enthalten.

L-Arginin und seine Derivate zeichnen sich auch durch ein besonders gutes Penetrationsvermögen aus.

Die erfindungsgemäßen basischen Aminosäuren, z.B. Arginin, Citrullin, Ornithin und Lysin und/oder ihre Derivate sind vorzugsweise in Mengen von 0,01 bis 30 Gew.-%. besonders bevorzugt 0,01 bis 10 Gew.-%, insbesondere 0,1 - 7,5 Gew.-%, jeweils bezogen auf die gesamte Zubereitung, in den erfindungsgemäßen kosmetischen und dermatologischen Zubereitungen enthalten. Die Wirkstoffe und deren Derivate können einzeln oder in Kombination eingesetzt werden. Zubereitungen enthalten jedoch vorzugsweise Arginin, besonders bevorzugt L-Arginin, in Mengen von 0,01 bis 10 Gew.-%, bezogen auf die gesamte Zubereitung.

Bevorzugt werden auch Kombinationen einer oder mehrerer der basischen Aminosäuren mit Folsäure.

Besonders geeignete Salze der Folsäure sind wasserlösliche Salze, insbesondere Natrium-, Kalium- und Ammoniumsalze.

Folsäure oder ihre Salze sind vorzugsweise in den erfindungsgemäßen Zubereitungen enthalten, bevorzugt jeweils in Mengen von 0,001 bis 5 Gew.-%, insbesondere 0,01 bis 1,5 Gew.-%, jeweils bezogen auf das Gesamtgewicht der Zubereitungen.

Die erfindungsgemäßen kosmetischen oder dermatologischen topischen Zubereitungen können auf an sich üblichen Formulierungsgrundlagen beruhen und zur Behandlung der Kopfhaut und der Haare im Sinne einer dermatologischen Behandlung oder einer Behandlung im Sinne der pflegenden Kosmetik dienen und werden in an sich bekannter Weise einmal oder mehrmals täglich an der Kopfhaut oder den Haaren angewendet.

Dermatologische und kosmetische Zubereitungen gemäß der Erfindung können in an sich bekannten Formen vorliegen. So können z.B. wäßrige, alkoholische oder wäßrig-alkoholische Lösungen, Emulsionen vom Typ Öl-in-Wasser (O/W), Emulsionen vom Typ Wasser-in-Öl (W/O), multiple Emulsionen z.B. vom Typ Wasser-in-Öl-in-Wasser (W/O/W), Gele, Hydrodispersionen, feste Stifte oder Aerosole die o.g. Wirkstoffkombinationen oder Wirkstoffe enthalten.

Bevorzugte Zubereitungen sind topische haarkosmetische Zubereitungen und zur Verwendung an der Kopfhaut geeignete und übliche Mittel.

Geeignete Haarbehandlungsmittel sind insbesondere Shampoo, Haarpflegemittel, Haarkonditioniermittel, Haarkur, Haarspülung, Haarfestiger, Haarverformungsmittel, Färbemittel, Tönungsmittel und Bleichmittel.

Die Zubereitungen gemäß der Erfindung können in verschiedener Form vorliegen, insbesondere als Lösungen, Gel, Creme, Öl, Emulsion oder jeder anderen zur Haut- und Haar-Behandlung geeigneten Form. Sie können auch als Aerosol in Gegenwart eines Treibmittels konditioniert sein.

Hierzu können, insbesondere auch für Haarbehandlungsmittel, zahlreiche kosmetisch annehmbare Bestandteile

verwendet werden. Die Zubereitungen können insbesondere enthalten: anionische, kationische, nichtionische, amphotere oberflächenaktive Mittel und deren Gemische. Unter den oberflächenaktiven Mitteln sind zu nennen: Alkylbenzolsulfonate, Alkylnaphthalinsulfonate, Sulfate, Ethersulfate und Fettalkoholsulfonate, quaternäre Ammoniumsalze, Fettsäurediethanolamide, polyoxyethylierte und polyglycerinierte Säuren und Alkohole, polyoxyethylierte und polyglycerinierte Alklyphenole, sowie polyoxyethylierte Alkylsulfate. Die oberflächenaktiven Produkte liegen in den Zubereitungen gemäß der Erfindung z.B. in Anteilen zwischen 0,5 und 55 Gew.-%, vorzugsweise zwischen 4 und 40 Gew.-%, bezogen auf das Gesamtgewicht der Zubereitung vor.

Die Zubereitungen können Wasser und auch organische Lösungsmittel enthalten, um die Verbindungen zu solubilisieren, die in Wasser nicht in ausreichendem Maße löslich sind. Unter den Lösungsmitteln können z.B. genannt werden: Niedrigalkanole, wie Ethanol und Isopropanol, Glycerin, Glykole oder Glykolether, wie Butoxy-2-ethanol, Ethylenglykol, Propylenglykol, Diethylenglykolmonoethyl- und monomethylether, sowie analoge Produkte und deren Gemische. Diese Lösungsmittel liegen vorzugsweise in Anteilen von 1 bis 40 Gew.-%, insbesondere von 5 bis 30 Gew.-%, bezogen auf das Gesamtgewicht der Zubereitungen vor.

Die Zubereitungen können vorzugsweise mit Kochsalz oder mit Verbindungen aus der Gruppe Natriumalginat, Gummiarabicum, Cellulosederivate, wie Methylcellulose, Hydroxyethylcellulose, Hydroxypropylethylcellulose, Carboxymethylcellulose und verschiedene Polymere, die diese Eigenschaften besitzen, wie insbesondere Acrylsäurederivate, verdickt werden. Es ist auch möglich, mineralische Verdickungsmittel zu verwenden, wie z.B. Bentonit. Diese Verdikkungsmittel liegen vorzugsweise in Anteilen zwischen 0,05 und 5 Gew.-%, bevorzugt zwischen 0,5 und 3 Gew.-%, bezogen auf das Gesamtgewicht der Zubereitungen vor.

Es ist natürlich möglich, den Zubereitungen gemäß der Erfindung jegliche andere Bestandteile zuzugeben, wie sie gewöhnlich verwendet werden, insbesondere Penetrationsagentien, Sequestrierungsagentien, filmbildenden Agentien, Puffer und Parfüme.

Schließlich können in den Zubereitungen noch weitere übliche kosmetische Zusätze, beispielsweise Antioxidantien wie Ascorbiensäure oder Natriumsulfit, Alkalisierungsmittel wie Alkalihydroxide, Ammonium- bzw. Alkalicarbonat und Ammonium- bzw. Alkalihydrogencarbonat, organische Säuren wie z.B. Essigsäure, Milchsäure und Zitronensäure, Lösungsmittel, Parfüm, Quellmittel, Netzmittel, Emulgatoren, Pflegestoffe und andere vorhanden sein.

Je nach Zusammensetzung können die erfindungsgemäßen Zubereitungen schwach sauer, neutral oder alkalisch reagieren.

Die erfindungsgemäßen topischen Zubereitungen, die insbesondere auch zur Behandlung der Kopfhaut dienen, können kosmetische Hilfsstoffe enthalten, wie sie üblicherweise in solchen Zubereitungen verwendet werden, z.B. Konservierungsmittel, Bakterizide, Parfüme, Mittel zum Verhindern des Schäumens, Farbstoffe, Pigmente, die eine färbende Wirkung haben, Verdickungsmittel, oberflächenaktive Substanzen, Emulgatoren, weichmachende Substanzen, anfeuchtende und/oder feuchhaltende Substanzen, Fette, Öle, Wachse oder andere übliche Bestandteile einer kosmetischen Formulierung wie Alkohole, Polyole, Polymere, Schaumstabilisatoren, Elektrolyte, organische Lösungsmittel oder Silikonderivate.

Sofern die kosmetische oder dermatologische Zubereitung eine Lösung oder Lotion darstellt, können als Lösungsmittel verwendet werden:

- Wasser oder wäßrige Lösungen;

- Öle, wie Triglyceride der Caprin- oder der Caprylsäure, vorzugsweise aber Rizinusöl;

- Fette, Wachse und andere natürliche und synthetische Fettkörper, vorzugsweise Ester von Fettsäuren mit Alkoholen niedriger C-Zahl, z.B. mit Isopropanol, Propylenglykol oder Glycerin, oder Ester von Fettalkoholen mit Alkansäuren niedriger C-Zahl oder mit Fettsäuren;

- Alkohole, Diole oder Polyole niedriger C-Zahl, sowie deren Ether, vorzugsweise Ethanol, Isopropanol, Propylenglykol, Glycerin, Ethylenglykol, Ethylenglykolmonoethyl- oder -monobutylether, Propylenglykolmonomethyl, -monoethyl- oder -monobutylelher, Diethylenglykolmonomethyl- oder -monoethylether und analoge Produkte.

Insbesondere werden Gemische der vorstehend genannten Lösungsmittel verwendet. Bei alkoholischen Lösungsmitteln kann Wasser ein weiterer Bestandteil sein.

Kosmetische und dermatologische Zubereitungen zur Behandlung und Pflege der Haut können als Gele vorliegen, die neben den Wirkstoffen und dafür üblicherweise verwendeten Lösungsmitteln noch organische Verdickungsmittel, z.B. Gummiarabikum, Xanthangummi, Natriumalginat, Cellulose-Derivate, vorzugsweise Methylcellulose, Hydroxymethylcellulose, Hydroxyethylcellulose, Hydroxypropylcellulose, Hydroxypropylmethylcellulose oder anorganische Verdikkungsmittel, z. B. Aluminiumsilikate wie beispielsweise Bentonite, oder ein Gemisch aus Polyethylenglykol und Polyethylenglykolstearat oder -distearat, enthalten. Das Verdickungsmittel ist in dem Gel z.B. in einer Menge zwischen 0,1 und 30 Gew.-%, bevorzugt zwischen 0,5 und 15 Gew.-%, enthalten.

Erfindungsgemäße Gele enthalten üblicherweise Alkohole niedriger C-Zahl, z.B. Ethanol, Isopropanol, 1,2-Propandiol, Glycerin und Wasser bzw. ein vorstehend genanntes Öl in Gegenwart eines Verdickungsmittels, das bei ölig-alkoholischen Gelen vorzugsweise Siliciumdioxid oder ein Aluminiumsilikat, bei wäßrig-alkoholischen oder alkoholischen Gelen vorzugweise ein Polyacrylat ist.

Hydrodispersionen stellen Dispersionen einer flüssigen, halbfesten oder festen inneren (diskontinuierlichen) Lipidphase in einer äußeren wäßrigen (kontinuierlichen) Phase dar.

Im Gegensatze zu O/W-Emulsionen, die sich durch eine ähnliche Phasenanordnung auszeichnen, sind Hydrodispersionen aber im wesentlichen frei von Emulgatoren. Hydrodispersionen stellen, wie im übrigen auch Emulsionen, metastabile Systeme dar und sind geneigt, in einen Zustand zweier in sich zusammenhängender diskreter Phasen überzugehen. In Emulsionen verhindert die Wahl eines geeigneten Emulgators die Phasentrennung.

Bei Hydrodispersionen einer flüssigen Lipidphase in einer äußeren wäßrigen Phase kann die die Stabilität eines solchen Systems beispielsweise dadurch gewährleistet werden, daß in der wäßrigen Phase ein Gelgerüst aufgebaut wird, in welchem die Lipidtröpfchen stabil suspendiert sind.

Feste Stifte gemäß der Erfindung können z.B. natürliche oder synthetische Wachse, Fettalkohole oder Fettsäureester enthalten.

Als Treibmittel für erfindungsgemäße, aus Aerosolbehältern versprühbare kosmetische oder dermatologische Zubereitungen sind die üblichen bekannten leichtflüchtigen, verflüssigten Treibmittel, beispielsweise Kohlenwasserstoffe (Propan, Butan, Isobutan) geeignet, die allein oder in Mischung miteinander eingesetzt werden können. Auch Druckluft ist vorteilhaft zu verwenden.

Die erfindungsgemäßen, z.B. topischen Zubereitungen, können die üblichen Hilfsstoffe, Emulgatoren und Konservierungsmittel enthalten.

Die erfindungsgemäßen Wirkstoffe, Wirkstoffkombinationen und die Zubereitungen, die sie enthalten, besitzen eine ausgeprägte Antischuppenwirkung. Sie sind zur Behandlung der Kopfschuppen und zur prophylaktischen Behandlung der Schuppenbildung der Kopfhaut und deren Schuppigkeit geeignet. Weiterhin erhöhen sie die Festigkeit der Haare. Sie dienen der Vorbeugung und Behandlung von gesplissenem Haar (Spliss) oder gebrochenem Haar oder in anderer Weise beschädigtem Haar, insbesondere dem Kopfhaar.

Gegenstand der Erfindung ist auch das Verfahren zur Herstellung der erfindungsgemäßen, z. B. topischen Zubereitungen, das dadurch gekennzeichnet ist, daß man in an sich bekannter Weise die Wirkstoffe in kosmetische oder dermatologische Formulierungen einarbeitet.

Alle Mengenangaben, Anteile und Prozentanteile sind, soweit nicht anders angegeben, auf das Gewicht und die Gesamtmenge bzw. auf das Gesamtgewicht der Zubereitungen bezogen.

Die nachfolgenden Beispiele sollen die vorliegende Erfindung verdeutlichen, ohne sie einzuschränken.

Beispiel 1

Shampoo (CTFA)	Gew.- %
Natriumlaurylethersulfat (2 EO, 20%)	40
Lauryl dimethylamino acetic acid betaine (30%)	4
Cocamide DEA, Coconut fatty acid diethanolamine	1.5
Oleth-3 phosphate, Oleyl triethoxy phosphate, (Briphos O3D, Albright & Wilson)	1
PEG-15 cocopolyamine, Polyglycol-polyamine condensation resin (Polyquart H, Henkel, 50%)	2
L-Argininhydrochlorid	5
Wasser, VES (vollentsalzt)	ad 100

Beispiel 1 a

Es wird wie in Beispiel 1 verfahren, und es werden 0,5 Gew.-% Folsäure zugegeben.

Beispiel 2

Hydrodispersion	Gew.-%
L-Ornithinhydrochlorid	1,0
Phenyltrimethicon	1,0
Carbomer (Carbopol 981)	1,0
Hydroxypropylmethylcellulose	0,2
Butylenglycol	3,0
Tromethamin	q.s.
NaOH-Lösung (15-Gew.-%ig)	q.s.
Ethanol	5,0
Parfum, Konservierungsmittel	q.s.
Wasser, VES	ad 100,0

Beispiel 2 a

An Stelle von L-Ornithinhydrochlorid wird die gleiche Gewichtsmenge L-Argininhydrochlorid zugegeben.

Beispiel 3

Lotion W/O	Gew.-%
L-Argininhydrochlorid	0,5
Folsäure	0,1
Cyclomethicon	3,0
PEG-1-Glycerin Sorbitan Oleostearat	1,7
PEG-7 Hydriertes Rizinusöl	6,3
Mineralöl (DAB 9)	13,9
Caprylic/capric Triglyceride	13,0
Magnesiumsulfat	0,7
Parfum, Konservierungsmittel	q.s.
Wasser, VES	ad 100

Beispiel 4

Haarwasser (Tonikum)	Gew.-%
L-Arginin	0,5
Ethanol	50
Wasser	ad 100

Beispiel 4 a

Es wird wie in Beispiel 4 angegeben verfahren, und es werden zusätzlich 0,5 Gew.-% Folsäure zugegeben.

Beispiel 5

W/O-Creme	Gew.-%
L-Argininhydrochlorid	2,5
L-Ornithinhydrochlorid	2,5
Folsäure	0,1
PEG-22-Dodecyl Glycol Copolymer	3,0
Cetyl Dimethicon Copolyol	2,0
Cyclomethicon	4,0
Mineralöl (DAB 9)	4,0
Caprylic/capric Triglyceride	4,0
Glycerin	4,00
Parfum, Konservierungsmittel	q.s.
Wasser, VES	ad 100,00

Beispiel 6

In den vorstehenden Beispielen können auch jeweils L-Citrullin oder L-Lysin in der Form ihrer Hydrochloride in den gleichen Gewichtsmengen an Stelle von Arginin oder Ornithin verwendet werden.

Die vorstehenden Zubereitungen können an der Kopfhaut und/oder den Haaren angewendet werden.

Patentansprüche

1. Verwendung von basischen Aminosäuren, insbesondere einer oder mehrerer Verbindungen, ausgewählt aus der Gruppe von Arginin, Ornithin, Citrullin und Lysin oder deren Salzen, Säureadditionssalzen, Estern oder Amiden, gegebenenfalls unter Zusatz von Folsäure oder deren Salzen, zur Prophylaxe und Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit.

2. Kosmetische und dermatologische Zubereitungen, insbesondere haarkosmetische Zubereitungen und Haarpflegeprodukte, welche die erfindungsgemäßen Wirkstoffe gemäß Anspruch 1 enthalten, und deren Verwendung zur Prophylaxe und Behandlung von Kopfschuppen und zur Verbesserung der Haarfestigkeit.

3. Wirkstoffe und Zubereitungen gemäß Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Wirkstoffe L-Arginin, L-Ornithin, L-Citrullin und/oder L-Lysin und/oder deren Derivate bzw. Salze sind.

4. Wirkstoffe und Zubereitungen gemäß den vorstehenden Ansprüchen, gekennzeichnet durch einen Gehalt an oder Zusatz von Folsäure und/oder deren Salzen.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/145,716	06/06/2005	Kevin P. Eaton	AZEAT.0001	3770

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DALLAS, TX 75380

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/145,716	EATON, KEVIN P.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claim 1 was amended and claims 18-24 were cancelled in an amendment filed 07 June 2007. As a result, claims 1-17 are pending and are thus examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Objections/Rejections

1. The objection to claims 18-24 under 37 CFR 1.75 as being a substantial duplicate of claims 11-17 is hereby **withdrawn** by the examiner in light of the aforementioned cancellation of claims 18-24.

2. The rejection of claims 1-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is hereby **withdrawn** by the examiner in light of the new ground of rejection presented herein below.

3. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby **withdrawn** by the examiner in light of the aforementioned amendment to claim 1 wherein the Markush group was amended to state, "the group *consisting* of..."

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis and dandruff with folic acid and vitamin B6, does not reasonably provide enablement for the treatment of all dermatological conditions with vitamin B12 alone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention
2) the state of the prior art
3) the relative skill of those in the art
4) the predictability of the art
5) the breadth of the claims
6) the amount of direction or guidance provided
7) the presence or absence of working examples
8) the quantity of experimentation necessary

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The claimed invention relates to a method of treating a dermatological condition by administering a vitamin supplement consisting essentially of a member selected from the group consisting of folic acid, vitamin B_6, vitamin B_{12}, a non-antioxidant vitamin and combinations thereof, as defined in instant claim 1. Claims 2-10 limit the dermatological condition to psoriasis, and claims 11-17 limit the dermatological condition to dandruff. However, the specification does not enable one skilled in the art to use the vitamin supplement consisting of vitamin B_{12} for the treatment of psoriasis and dandruff. Vitamin B_{12} is known to help in the formation and regeneration of red blood cells, thus helping prevent anemia, necessary for carbohydrate, fat and protein metabolism, maintains a healthy nervous system, promotes growth in children, increases energy, and is needed for calcium absorption (U.S. 7,115,286, col. 19, ll. 54-59). U.S. Patent No. 6,107,349 teaches that administration of vitamin E, evening primrose oil, or B-complex vitamins alone do not produce significant improvements in psoriasis (column 3, lines 32-41). The '349 patent discloses B-complex vitamins comprise several B vitamins, including folic acid, vitamin B_6 and vitamin B_{12} (column 4, lines 10-16). Therefore, absent a disclosure to the contrary, the prior art teaches that vitamin B_{12} alone is not capable of treating psoriasis. Any element critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Therefore, any element that is critical to practice the invention must be recited in the claims.

Response to Arguments

Applicants argue on pages 6 and 7 of their Remarks filed 07 June 2007 that Mantynen, the '349 patent, does not teach that the compositions of the instant claims are incapable of treating psoriasis. However, the examiner contends that the instant specification has not shown any evidence that vitamin B_{12} of the instant claims will have any beneficial effect toward any dermatological condition. Moreover, Mantynen evidences the lack of utility in treating psoriasis because a lack of significant improvement means that there is not a sufficient affect to warrant an improvement of psoriasis. Therefore, in the absence of evidence to the contrary, the examiner contends that vitamin B_{12} alone is not enabled in treating dermatological conditions.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,107,349 (Mantynen).

Mantynen discloses the use of a specific combination of Vitamin E, evening primrose oil and 50-200 μg of B-complex vitamins, including 0.4-1.6 mg folic acid, for treatment of psoriasis (col. 3, ll. 32-34 and 55-57). Mantynen also discloses that B-complex vitamins, including vitamin B-6, Vitamin B-12, and folic acid (col. 3, ll. 62-65; and col. 4, ll. 10-16), were applied alone to psoriasis, but did not produce significant improvement (col. 3, ll. 37-41). Therefore, Mantynen discloses applying B-complex vitamins to psoriasis, which anticipates the instant claims.

2. Claims 1-4, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0132800 (Popp et al.).

Popp et al. disclose that psoriasis patients are known to be deficient in folic acid, and supplementation with folic acid may benefit psoriasis and seborrheic dermatitis (i.e. dandruff) patients ([0031]).

3. Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,115,286 (Meredith).

Meredith discloses that sufferers of psoriasis may consider taking extra folic acid, and folic acid is more effective when taken with the B group vitamins-especially vitamin B12 and vitamin B6 (col. 16, ll. 22-23 and 34-36). Meredith also discloses that vitamin B6 (i.e. pyridoxine) reportedly may assist in the prevention of dandruff, eczema and psoriasis (col. 18, ll. 36-39).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nathan W. Schlientz
Patent Examiner
Technology Center 1600
Group Art Unit 1616

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616

Notice of References Cited	Application/Control No. 11/145,716	Applicant(s)/Patent Under Reexamination EATON, KEVIN P.	
	Examiner Nathan W. Schlientz	Art Unit 1616	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0132800	09-2002	Popp et al.	514/168
*	B	US-6,107,349	08-2000	Mantynen, Philip R.	424/776
*	C	US-7,115,286	10-2006	Meredith, Sarah	424/725
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	Art Unit
	Schlientz, Nathan W	1616

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/26/2007	01/23/2008							
	1	✓	✓							
	2	✓	✓							
	3	✓	✓							
	4	✓	✓							
	5	✓	✓							
	6	✓	✓							
	7	✓	✓							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	✓	✓							
	18	O	-							
	19	O	-							
	20	O	-							
	21	O	-							
	22	O	-							
	23	O	-							
	24	O	-							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11145716	EATON, KEVIN P.
	Examiner	Art Unit
	Schlientz, Nathan W	1616

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
EAST (history attached)	2/4/08	NWS
Inventor Name Search (PALM and EAST)	2/4/08	NWS

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	2	"145716".ap.	US-PGPUB	ADJ	ON	2007/01/17 17:57
S2	3	("5932624"|"6265391"|"6605646").PN.	USPAT	ADJ	ON	2007/01/17 17:58
S3	2622	514/52,251,276,350,356.ccls.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 17:58
S4	14485	folic acid	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 17:59
S5	6684	vitamin b12	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 17:59
S6	3794	vitamin b6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 18:00
S7	1151	S4 and S5 and S6	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 17:59
S8	138	S7 and S3	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/17 17:59
S16	1630	folic acid.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:23

EAST Search History

S17	525	vitamin b12.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:17
S18	459	vitamin b6.clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 09:49
S19	195	S16 and S17 and S18	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:02
S20	13	S19 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:25
S21	9	S19 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:25
S22	1068	S16 and (vitamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:03
S23	26	S22 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:15
S24	13	S22 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:15

EAST Search History

S26	813	(vitamin b12 or cyanocobalamin or cobalamin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:25
S27	1322	(vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S28	2084	(folic acid or folate or pteroyl$glutamic acid or Vitamin B9 or Vitamin M or Folacin).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S29	388	S26 and S27 and S28	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S30	23	S29 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:28
S31	9	S29 and (psoriasis or dandruff).clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:25
S32	9456	vitamin b12 or cyanocobalamin or cobalamin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:25
S33	15633	vitamin b6 or pyridoxine or pyridoxal or pyridoxamine or $pyridoxic acid	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26

EAST Search History

S34	19590	folic acid or folate or pteroyl$glutamic acid or Vitamin B9 or Vitamin M or Folacin	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S35	3032	S32 and S33 and S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S36	2457	S32 same S33 same S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:26
S37	1853	S32 with S33 with S34	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:27
S42	486	S35 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:28
S43	230	S36 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:28
S44	195	S37 and (psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:32
S45	38	S35 and (psoriasis or dandruff). clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:29

EAST Search History

S46	37	S36 and (psoriasis or dandruff). clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:29
S47	32	S37 and (psoriasis or dandruff). clm.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:29
S48	32	S37 and dandruff	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2007/01/18 10:32
S49	2	psoriasis with may benefit with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 09:53
S50	97	psoriasis with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 09:55
S51	1678	folic acid with b6	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 09:56
S52	8	S50 and S51	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 09:56

EAST Search History

S53	4	dandruff with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 10:19
S54	1	"20020132800"	US-PGPUB	ADJ	ON	2008/02/04 10:47
S55	6	(dandruff or seborrheic dermatitis) with folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 10:56
S56	16	(dandruff or seborrheic dermatitis) same folic acid	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 10:57
S57	5979	eaton.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 11:28
S58	390	S57 and (folic acid or vitamin B6 or vitamin B12 or psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 11:29
S59	450	eaton.in. and kevin.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 11:29
S60	186	S59 and (folic acid or vitamin B6 or vitamin B12 or psoriasis or dandruff)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	ADJ	ON	2008/02/04 11:29

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/145,716	06/06/2005	Kevin P. Eaton	AEATO.0001	3770

22858 7590 02/07/2007
CARSTENS & CAHOON, LLP
P O BOX 802334
DALLAS, TX 75380

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

Claims 1-24 are pending. No claim is allowed at this time.

Claim Objections

Claims 18-24 are objected to because of the following informalities: Claims 18-24 are substantial duplicates of claims 11-17. The Applicant should cancel one of these sets of claims, or one of these sets of claims will be cancelled if they are found to be allowable.

Information Disclosure Statement

The information disclosure statement filed 10 February 2006 contains two Non-Patent Literature documents, wherein only the abstract is provided (Jungkeit et al. and Filimonkova et al.). These documents have been considered only with respect to the disclosure of the abstract.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement with respect to how to use the claimed

invention. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The claims are drawn to treating a dermatological disorder, namely psoriasis and dandruff, through application of a vitamin supplement consisting essentially of folic acid, vitamin B_6, vitamin B_{12}, and/or non-antioxidant vitamins. However, the specification does not enable one skilled in the art to use the vitamin supplement as claimed for the treatment of psoriasis and dandruff. U.S. Patent No. 6,107,349 teaches that administration of vitamin E, evening primrose oil, or B-complex vitamins alone do not produce significant improvements in psoriasis (column 3, lines 32-41). The '349 patent discloses B-complex vitamins comprise several B vitamins, including folic acid, vitamin B_6 and vitamin B_{12} (column 4, lines 10-16). Therefore, absent a disclosure to the contrary, the prior art teaches the instantly claimed composition is not capable of treating psoriasis. Any element critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Therefore, any element that is critical to practice the invention must be recited in the claims.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

PTO/SB/05 (09-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	AEATO.0001
First Inventor	Eaton
Title	Treatment of Dermatological Conditions
Express Mail Label No.	EV 652889402 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☑ **Fee Transmittal Form** (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 10] Both the claims and abstract must start on a new page *(For information on the preferred arrangement, see MPEP 608.01(a))*
4. ☐ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* _____]
5. **Oath or Declaration** [*Total Sheets* 3]
   a. ☑ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)* ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission** *(if applicable, items a. – c. are required)*
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

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P.O. Box 1450
Alexandria VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee _____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☑ **Return Receipt Postcard** (MPEP 503) *(Should be specifically itemized)*
15. ☐ **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☑ Other: check in the amount of $600.00

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

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Signature		Date	June 6, 2005
Name (Print/Type)	Casey L. Griffith	Registration No. (Attorney/Agent)	47,610

APPLICATION FOR

UNITED STATES LETTERS PATENT

FOR

TREATMENT OF DERMATOLOGICAL CONDITIONS

BY:

KEVIN P. EATON

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TREATMENT OF DERMATOLOGICAL CONDITIONS

BACKGROUND

1. Cross Reference to Related Application

This application claims the benefit of U.S. Provisional application Serial No. 60/577,294, filed June 4, 2004, which is incorporated herein by this reference.

2. Technical Field

The present invention relates generally to the treatment of dermatological conditions, including but not limited to psoriasis, dermatitis, and dandruff. More specifically, the invention relates to the treatment of said dermatological conditions using a multiple vitamin supplement composition.

3. Background of the Invention

Dermatological conditions such as psoriasis, dermatitis, and dandruff affect millions of people every year in the United States alone. Psoriasis typically is characterized by dry, red patches of skin covered with silvery scales; sometimes pustules appear on top of said patches. Depending on the type of dermatitis, the following symptoms may occur: redness and itching, accompanied in severe cases by blisters and weeping sores; thickened, brownish skin; itchy, thickened, scaly skin; greasy, scaling areas at the sides of an individual's nose, between the eyebrows, behind the ears or over the breastbone; discolored (red or brown), thick and itchy skin around the shins and ankles, occasionally developing open sores or ulcers; skin around the mouth exhibiting small red bumps, pus-filled bumps or mild peeling. Signs of dandruff, of course, are white, oily-looking flakes of dead skin that dot an individual's hair and shoulders and an itchy, scaling scalp. These dermatological conditions plainly have a significant negative impact on the public appearance of afflicted individuals.

Several methods exist in the prior art for treating these dermatological conditions. Dandruff, for example is commonly treated using medicated shampoos. Depending on the type of dermatitis, creams, lotions, ointments, or oral medications are prescribed.

Psoriasis, a persistent, chronic disease, also has been treated using creams, ointments, and oral medications, as well as phototherapy and biologic drugs. All of the existing treatments vary in effectiveness and their drawbacks. For instance, while existing oral medications may effectively treat even severe cases of psoriasis, significant negative side effects often result, including eye and lip inflammation, bone spurs, hair loss, liver and kidney toxicities, and birth defects if taken during pregnancy.

Therefore, it would be desirable to have a way of effectively treating dermatological conditions such as psoriasis, dermatitis, and dandruff.

SUMMARY OF THE INVENTION

The present invention is a treatment for dermatological conditions such as psoriasis, dermatitis, and dandruff using a vitamin supplement composition comprising folic acid, vitamin B_{12} and/or vitamin B_6. The vitamin supplement composition may also be essentially free of antioxidants.

By "essentially free" it is meant that the vitamin composition should not contain an amount of antioxidants which would tend to damage and inactivate some of the vitamin B_{12} and/or folic acid of the vitamin supplement. The presence of lower amounts of antioxidants would not render the vitamin composition of the present invention ineffective or of reduced effectiveness.

In accordance with an aspect of the present invention there is a provided a method of administering a multiple vitamin supplement composition for the treatment of dermatological conditions such as psoriasis, dermatitis and dandruff.

DETAILED DESCRIPTION OF THE INVENTION

Therapeutic treatment of dermatological conditions such as psoriasis, dermatitis, or dandruff with the vitamin supplement composition of the present invention may involve administration to persons prophylactically. That is, to prevent, retard or reduce the severity of future occurrence of such dermatological conditions.

The multiple vitamin supplement composition of the present invention contains a therapeutically effective amount of folic acid, vitamin B_{12} and may or may not also contain vitamin B_6. The composition may also be essentially free of antioxidants. The vitamin composition may be administered with a pharmaceutically acceptable carrier. A pharmaceutically acceptable carrier may be any compatible, non-toxic substance suitable to deliver the components. The supplement may contain other pharmaceutically acceptable substances as required to approximate physiological conditions such as a pH adjusting and buffering agent, disbursing agents, toxicity adjusting agents, flavoring agents and like. The concentration of the components in these formulations may vary and will be selected primarily on the particular dosage and mode of administration selected. Methods for preparing supplements are well-known or will be apparent to those skilled in the art and are described in more detail in, for example, *Remington's Pharmaceutical Science*, 15th ed., Mack Publishing Company, Easton, Pa.

The vitamin supplement composition is useful for oral administration. Indeed, the supplement is preferably administered orally. For oral administration, solid or fluid dosage forms can be prepared. For preparing solid compositions such as tablets, the components are mixed with conventional ingredients, such as talc, magnesium stearate, and functionally similar materials, as pharmaceutical carriers. Capsules are prepared by mixing the components with an inert pharmaceutical diluent and filling the mixture into a hard gelatin capsule. Soft gelatin capsules are prepared by machine encapsulation of a slurry of the components with an acceptable vegetable oil, light liquid petrolatum or other inert oil. Fluid unit dosage forms for oil administration such as serum and suspensions can be prepared. The components may be dissolved in an aqueous vehicle together with sugar, sweetening and flavoring agents and preservatives to form a serum. Suspensions can be prepared with an aqueous vehicle and a disbursing agent such as acacia, tragacanth, methylcellulose and the like.

In the case of a vitamin supplement compound that is essentially free of antioxidants, among the antioxidants especially to be avoided is added vitamin C, and no antioxidants of any kind should be added to any of the compounds disclosed herein (although such antioxidants may be present during the preparation of such vitamins provided that they are removed afterward, either completely or at least to a level where they have virtually no effect on the vitamin components of the present invention). Because antioxidants may be present in vitamin preparations useful in forming the compounds of the present invention, the present invention also relates to processes wherein the folic acid, vitamin B_{12} and/or vitamin B_6 has been tested for the presence of antioxidant and shown to be free of antioxidant. Such testing is commonly performed by liquefying a sample of the product (i.e., the vitamin, or vitamin compound, or medicament) to be tested in a solution at stomach pH, and another sample at neutral pH, incubating for 30 minutes (the gastric half- emptying time) and then assaying the amount of vitamin, or vitamins, remaining as compared to the amount prior to incubation. Note also that in the case of a vitamin supplement compound that is meant to be essentially free of antioxidants, any carrier, filler or other substance associated with the components of the invention used to prepare a tablet, capsule or the like should also be essentially free of anti-oxidants.

Separate vitamin supplement compositions may be prepared with each containing only folic acid, vitamin B_{12} or vitamin B_6. Each of these tablets may also, if necessary, be essentially free of antioxidants. In this manner, one component of folic acid, vitamin B_{12} or vitamin B_6 can be taken alone such that a user, or their physician, may have more control over the quantity of intake of folic acid, vitamin B_{12} or vitamin B_6, without being forced to also alter the level of intake of the others. This also allows for only folic acid, vitamin B_{12} or vitamin B_6 to be administered when appropriate.

The vitamin supplement composition may be administered in dosages and over a period of time with a frequency and duration sufficient to yield a therapeutically effective amount, i.e., an amount sufficient to curtail the severity of or eliminate the symptoms of the dermatological condition being treated. Unit dosages effective for this use will vary, but will generally range from 25 to about 2,200 micrograms of folic acid, 25 to about

2,500 micrograms of vitamin B_{12}, and 0.5 to about 20 milligrams of vitamin B_6. Preferably, the vitamin supplement composition will have unit dosages of 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6, and will be essentially free of antioxidants.

CLAIMS

I claim:

1. A method of treating a dermatological condition by administering to a person a vitamin supplement composition consisting essentially of a member selected from the group of:

(a) folic acid;

(b) vitamin B_{12};

(c) vitamin B_6;

(d) folic acid and vitamin B_{12};

(e) folic acid and vitamin B_6;

(f) vitamin B_{12} and vitamin B_6;

(g) folic acid, vitamin B_{12}, and vitamin B_6;

(h) folic acid, vitamin B_{12}, and a non-antioxidant vitamin; and

(i) folic acid, vitamin B_{12}, and non-antioxidant vitamins.

2. The method of claim 1 wherein said dermatological condition is psoriasis.

3. The method of claim 2 wherein said composition is essentially free of anti-oxidants.

4. The method of claim 3 wherein said member has been tested for the presence of antioxidant and shown to be free of antioxidant.

5. The method of claim 3 wherein said member is folic acid and vitamin B_{12}.

6. The method of claim 5 wherein said composition comprises at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

7. The method of claim 6 wherein said composition further comprises from at least about 0.5 milligrams to about 20 milligrams of vitamin B_6.

8. The method of claim 7 wherein said composition is in the form of a tablet.

9. The method of claim 7 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

10. The method of claim 9 wherein said composition is in the form of a tablet.

11. The method of claim 1 wherein said dermatological condition is dandruff.

12. The method of claim 11 wherein said composition is essentially free of anti-oxidants.

13. The method of claim 12 wherein said member is folic acid and vitamin B_{12}.

14. The method of claim 13 wherein said composition comprises at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

15. The method of claim 14 wherein said composition further comprises from at least about 0.5 milligrams to about 20 milligrams of vitamin B_6.

16. The method of claim 15 wherein said composition is in the form of a tablet.

17. The method of claim 15 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

18. The method of claim 1 wherein said dermatological condition is dandruff.

19. The method of claim 18 wherein said composition is essentially free of anti-oxidants.

20. The method of claim 19 wherein said member is folic acid and vitamin B_{12}.

21. The method of claim 20 wherein said composition comprises at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

22. The method of claim 21 wherein said composition further comprises from at least about 0.5 milligrams to about 20 milligrams of vitamin B_6.

23. The method of claim 22 wherein said composition is in the form of a tablet.

24. The method of claim 22 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

TREATMENT OF DERMATOLOGICAL CONDITIONS

ABSTRACT

The present invention provides a method for treating dermatological conditions, such as psoriasis, dermatitis, and dandruff. Said conditions are treated by administering to a person a vitamin supplement composition comprising folic acid, vitamin B_{12} and/or vitamin B_6. The vitamin supplement composition may also be essentially free of antioxidants

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	**Kevin Eaton**
Serial No:	**[NEW]**
Filing Date:	**June 6, 2005**
Title:	**Treatment of Dermatological Conditions**
Attorney Docket No.:	**AEATO.0001**

DECLARATION AND POWER OF ATTORNEY

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original inventor of the subject matter which is claimed and for which a patent is sought on the invention, design or discovery entitled:

TREATMENT OF DERMATOLOGICAL CONDITIONS

the specification of which is identified above.

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose to the Office all information known to me to be material to the patentability of this application as defined by Title 37, Code of Federal Regulations, § 1.56.

I hereby claim no foreign priority benefits under 35 U.S.C. § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate.

I hereby claim the benefit, under 35 U.S.C. § 119(e)(1), of U.S. Provisional application Serial No. 60/577,294, filed June 4, 2004.

I hereby claim no benefit under 35 U.S.C. § 120 of any United States application for patent.

I acknowledge the duty to disclose to the Office all information known to me to be material to patentability as defined in § 1.56 which became available between the

filing date of any prior application(s) and the national or PCT international filing date of this application.

I hereby **appoint:**

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Colin P. Cahoon	**Registration No. 38,836**
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Jeffrey G. Degenfelder	**Registration No. 44,647**
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each with the firm of Carstens & Cahoon, L.L.P., my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, and to file and prosecute any international patent applications filed thereon before any international authorities under the Patent Cooperation Treaty.

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Attorney Docket No.: **AEATO.0001**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of Sole Inventor: **Kevin P. Eaton**

Inventor's Signature: Kevin P. Eaton Date: 6·3·05

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PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

06/08/2005 CNGUYEN2 00000023 11145716

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP
04 FC:2202	100.00 OP

PTO-1556
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11/145,716

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	24 minus 20 =	* 4	X$ 25 =	100	OR	X$50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*	X100 =			X200 =	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	600		TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO 09-7087

CC=DE
DATE=20020508
KIND=A1
PN=10053155

USE OF A MULTIVITAMIN PREPARATION FOR THE TREATMENT OF PSORIASIS [VERWENDUNG EINES MULTIVITAMINPRÄPARATS ZUR BEHANDLUNG DER SCHUPPENFLECHTE]

ERIKA JUNGKEIT

UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. AUGUST 2009
TRANSLATED BY SCHREIBER TRANSLATIONS, INC.

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INVENTOR(S)	(72):	ERIKA JUNGKEIT
APPLICANT(S)	(71):	ERIKA JUNGKEIT
DESIGNATED CONTRACTING STATES	(81):	
TITLE	(54):	USE OF A MULTIVITAMIN PREPARATION FOR THE TREATMENT OF PSORIASIS
FOREIGN TITLE	[54A]:	VERWENDUNG EINES MULTIVITAMINPRÄPARATS ZUR BEHANDLUNG DER SCHUPPENFLECHTE

/1

[0001] Psoriasis is one of the most frequent skin diseases, whose genesis, despite numerous theories, has still not been clarified to date. Accordingly, there is also no reliable medicamentous therapy. Medicamentous aid addresses primarily the symptoms of the disease, in order to alleviate the phenomena which appear at the disease foci of the skin, and in particular to reduce the associated pain. Along with the cortisone preparations suited for this, which to be sure also produce undesired side effects, there are numerous agents likewise provided for local treatment, which are produced on the basis of coal tar, urea, salicylic acid, selenium disulfide, finely dispersed sulfur, or the like. There is therefore no medicamentous treatment known with which the impairments of psoriasis can be eliminated sustainably with as few side effects as possible.

[0002] The invention is thus based on the problem of making such a medicamentous treatment possible.

[0003] Proceeding from this problem, in accordance with the invention, the use of a multivitamin preparation containing vitamin B1, vitamin B2, nicotine amide, dexpanthenol, biotin, folic acid, vitamin B6, vitamin B12, vitamin C, and vitamin E is specified for the treatment of psoriasis.

[0004] Quite surprisingly, it has been found that such a multivitamin preparation in the usual dosage and utilized for several months, even after a few weeks, leads to a perceptible remission of

the psoriasis and that after a few months, complete pain-freedom ensues, although the psoriasis at this point is not yet fully healed. Full healing occurs after a significantly longer time.

[0005] The multivitamin preparation comprises multivitamin capsules that are marketed under the name Multibionta forte N of the Merck Company. The utilized capsules contain:

Thiamine-HCl (Vit. B_1)	15 mg
Riboflavin (Vit. B_2)	12.5 mg
Nicotine amide	60 mg
Dexpanthenol	10 mg
Biotin	150 µg
Folic acid	500 µg
Pyridoxine-HCl (Vit. B_6)	20 mg
Cyanocobalamine (Vit. B_{12})	150 µg
Ascorbic acid (Vit. C)	200 mg
DL-Tocopherol acetate	74.5 mg (corresponding to 50 mg of Vit. E)

[0006] Other components of the preparation include:

Partially hardened vegetable oils

Mid-chain triglycerides

Yellow wax

Soy-derived lecithin

Flavoring agent

Gelatin

Glycerin

Anidrisorb

Color iron oxides

[0007] The provided area of application of these capsules is directed toward vitamin deficiency symptoms, which psoriasis is not considered to be. In connection with the treatment of psoriasis or other hyper- or dyskeratosis, at the most high-dose, vitamin A (retinol) (far above the normal daily requirement of an adult of 2 mg) has been discussed as a vitamin active ingredient. The capsules utilized in accordance with the invention do not contain any vitamin A, however, but solely the above vitamin complex. The effectiveness of the multivitamin preparation identified in accordance with the invention is therefore not explainable with the conventional theories.

[0008] The effectiveness of the multivitamin preparation was determined in three randomly selected patients.

Example 1

[0009] A patient, just turned 50 years of age, suffered from an attack of psoriasis on the insides of the hands and fingers to under the nails, as well as on the soles of the feet. The skin was cracked at the affected sites, and the attack was associated with intense pains.

[0010] After years of unsuccessful treatment by various private physicians and at a university clinic, she began to take a

multivitamin preparation (Multibionta forte N-capsules, one capsule per day). After $1^1/_2$ months, the psoriasis receded perceptibly. After about 4 months, pain-freedom set in. The skin was no longer cracked, but was still very sensitive and irritated. About 12 months passed before total healing. Since then, the skin has been delicate and smooth, with no damage whatsoever.

[0011] To be sure, the healing is tied to the further use of the multivitamin capsules. After discontinuation of the multivitamin preparation, the psoriasis breaks out again at the previously affected sites after a few days.

Example 2

[0012] Patient in her early 40s, suffered from an extremely intense attack of psoriasis on both feet. It was impossible to wear normal shoes. The skin was bloody and cracked. About 2 months after the start of using Multibionta forte N capsules (one capsule per day), the patient was pain-free. After around 3 months, she could wear normal shoes again for the first time. The skin is no longer bloody and cracked, and is slowly building back up. The treatment is being continued.

Example 3

[0013] Patient, 32 years old, with an attack of psoriasis on both arms with intensely itchy skin rashes. She was treated with a cortisone cream for the itchiness.

[0014] After around 2 months of taking one capsule of Multibionta forte N a day, the itchiness receded strongly, so that the cortisone cream could be discontinued. The reddening of the affected sites has receded. The treatment is being continued without any other medication.

[0015] The multivitamin preparations of the type used here normally have no side effects, and are suited for a long-term treatment until possible final healing and/or renewed treatment if the symptoms of psoriasis should recur.

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Claims

1. Use of a multivitamin preparation containing vitamin B_1, vitamin B_2, nicotine amide, dexpanthenol, biotin, folic acid, vitamin B_6, vitamin B_{12}, vitamin C, and vitamin E for the treatment of psoriasis.

2. Use of a multivitamin preparation in accordance with claim 1 with the following composition:

Vitamin B_1	15 mg
Vitamin B_2	12.5 mg
Nicotine amide	60 mg
Dexpanthenol	10 mg
Biotin	150 µg
Folic acid	500 µg
Vitamin B_6	20 mg

Vitamin B_{12}	150 µg
Vitamin C	200 mg
Vitamin E	50 mg.

3. Use of a multivitamin preparation in accordance with claim 1 or 2, which contains no vitamin A or vitamin A ≤ 2 mg.

/3

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US007115286B2

(12) **United States Patent**
Meredith

(10) **Patent No.: US 7,115,286 B2**
(45) **Date of Patent: Oct. 3, 2006**

(54) **COMPOSITIONS AND METHODS FOR AN ORALLY ADMINISTERED INHIBITOR OF BITING INSECTS**

(76) Inventor: **Sarah Meredith**, 24 Kendall St., Laguna Niguel, CA (US) 92677

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 10 days.

(21) Appl. No.: **10/862,261**

(22) Filed: **Jun. 7, 2004**

(65) **Prior Publication Data**

US 2005/0008656 A1 Jan. 13, 2005

Related U.S. Application Data

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(51) **Int. Cl.**
A61K 36/00 (2006.01)

(52) **U.S. Cl.** **424/725**; 424/195.17; 424/745; 424/747; 424/750

(58) **Field of Classification Search** 424/725, 424/195.17, 745, 747, 750
See application file for complete search history.

(56) **References Cited**

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(57) **ABSTRACT**

The present disclosure concerns methods and compositions to inhibit insects from biting a subject. In preferred embodiments, the compositions may be administered orally, for example using a spray bottle to deliver to the mouth. In certain embodiments, the compositions and methods are effective to reduce swelling, itching, redness and/or inflammation of the local area of an insect bite. The compositions may include one or more herbs selected from the group consisting of rice bran, peppermint, barley grass, *lobelia; chlorella,* watercress, alfalfa and parsley and one or more vitamins selected from the group consisting of thiamin (B-1), riboflavin (B-2), niacin (B-3), pantothenic acid (B-5), pyridoxine (B-6), folic acid (B-9), cyanocobalamin (B-12), choline, inositol, d-biotin, para-aminobenzoic acid, and lecithin. Administration of effective amounts of the compositions is sufficient to inhibit insects from biting and/or treat insect affected areas of a subject.

9 Claims, No Drawings

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COMPOSITIONS AND METHODS FOR AN ORALLY ADMINISTERED INHIBITOR OF BITING INSECTS

RELATED APPLICATIONS

The present application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Ser. No. 60/485,421, filed Jul. 8, 2003, the entire text of which is incorporated herein by reference.

BACKGROUND

1. Field

The following embodiments relate to inhibitors of biting insects and more particularly to compositions and methods for reducing the incidence of insect bites. Even more particularly, the disclosed compositions and methods inhibit biting insects, for example mosquitoes, from biting a subject after landing on a subject. In some embodiments, such inhibitors may also be used, for example, to reduce swelling, inflammation and/or itching after an insect bite. In various embodiments, the compositions may be administered orally to inhibit insects from biting subjects.

2. Background

Multiple species of flying and crawling insects, including mosquitoes, ticks, flies, midges, chiggers, and fleas, bite subjects, such as human subjects. Although such insects are mostly a nuisance in North America, they transmit more than 100 bacterial, protozoan, parasitic, and rickettsial diseases to humans worldwide.

Mosquitoes transmit more diseases to humans than any other biting insect. Mosquitoes are the vectors responsible for transmitting several forms of viral encephalitis, yellow fever, dengue fever, bancroftian filariasis, and epidemic polyarthritis to humans; more than 700,000,000 people are infected yearly. Malaria, which is transmitted by the bite of a mosquito infected with the single-cell protozoan *Plasmodium*, is responsible for 3,000,000 deaths annually (Fradin MS: Mosquitoes and mosquito repellents: a clinician's guide. Ann Intern Med Jun. 1, 1998 ; 128(11): 931–40).

There are over 2500 different species of mosquitoes throughout the world, of which 150 species occur in the United States. A single female mosquito can lay over 200 eggs at a time. Mosquito eggs can survive for more than five years. All mosquitoes need water to complete their life cycle. Not all species bite humans; some prefer birds, others prefer horses, and some will even bite frogs and turtles. Only females take blood; males feed only on plant nectar. Mosquitoes can fly considerable distances; some species remain close to their larval habitats while others can fly 20 miles or more. Mosquitoes do not develop in grass or shrubbery, although adults frequently rest in these areas during daylight hours. Mosquitoes are responsible for more human deaths than any other living creature.

West Nile Virus (WNV) is a flavivirus belonging taxonomically to the Japanese encephalitis serocomplex that includes the closely related St. Louis encephalitis (SLE) virus, Kunjin and Murray Valley encephalitis viruses, as well as others. WNV was first isolated in the West Nile Province of Uganda in 1937. The first recorded epidemics occurred in Israel during 1951–1954 and in 1957. Epidemics have been reported in Europe in the Rhone delta of France in 1962 and in Romania in 1996. The largest recorded epidemic occurred in South Africa in 1974.

An outbreak of arboviral encephalitis in New York City and neighboring counties in New York state in late August and September 1999, was subsequently confirmed as caused by West Nile virus, based on the identification of virus in human, avian, and mosquito samples.

Although it is not known when and how West Nile virus was introduced into North America, international travel of infected persons to New York or transport by imported infected birds may have played a role. WNV can infect a wide range of vertebrates; in humans it usually produces either asymptomatic infection or mild febrile disease, but can cause severe and fatal infection in a small percentage of patients. Within its normal geographic distribution of Africa, the Middle East, western Asia, and Europe, WNV has not been documented to cause epizootics in birds. Crows and other birds with antibodies to WNV are common, suggesting that asymptomatic or mild infection usually occurs among birds in those regions. Similarly, substantial bird virulence of SLE virus has not been reported. Therefore, an epizootic producing high mortality in crows and other bird species is unusual for either WNV or SLE virus. For both viruses, migratory birds may play an important role in the natural transmission cycles and spread. Like SLE virus, WNV is transmitted principally by *Culex* species mosquitoes, but also can be transmitted by *Aedes, Anopheles*, and other species. The predominance of urban *Culex pipiens* mosquitoes trapped during this outbreak suggests an important role for this species. By August 2002, the WNV, carried by mosquitoes, had spread to 41 states, causing a total of 24 fatalities.

Infected ticks can transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, tularemia, and tick paralysis. Flies are the vectors responsible for transmitting other diseases such as African trypanosomiasis, leishmaniasis, onchocerciasis, and loiasis to humans. Fleabites may transmit plague, and, in South America, kissing bugs transmit Chagas disease.

Despite the need for an effective oral inhibitor of biting insects, no such agent has been identified thus far. Ingested garlic, brewer's yeast, and thiamine are not effective at inhibiting insects from biting. The quest to develop the perfect topical insect repellent has been an ongoing scientific goal for years but has yet to be achieved.

The ideal insect inhibitor and/or repellent would provide protection from multiple species of biting arthropods; remain effective for at least 8 hours; cause no irritation to the skin or mucous membranes; exhibit no systemic toxicity; be resistant to abrasion and wash-off; and be greaseless and odorless, i.e., cosmetically appealing.

A distinction is made herein between insect repellents, which prevent biting insects from landing on a subject, and inhibitors of biting insects, which inhibit insects from biting a subject after landing. Although a particular composition may have efficacy as both an inhibitor and a repellant of biting insects, commercially available formulations typically act as insect repellants. Commercial insect repellents may generally be characterized as involving topical application, usually are effective for limited duration, may cause severe irritation of skin or mucous membranes, may be abraded or washed off, possess a pungent odor and greasy texture, and arguably may have toxic side effects.

To be effective, an insect repellent should be volatile enough to maintain an effective vapor concentration at the skin surface, but it must not evaporate so rapidly that it quickly loses its effectiveness. Multiple factors play a role in effectiveness, including the concentration, frequency, and uniformity of application; the user's activity level and overall attractiveness to blood-sucking arthropods; and the number and species of potentially biting insects. The effec-

tiveness of any insect repellent is reduced by abrasion from clothing; evaporation and absorption from the skin surface; wash-off from sweat, rain, or water; a windy environment; and high ambient temperatures. Each 10° C. increase in temperature may lead to as much as a 50% reduction in protection time. (www.emedicine.com/derm/topics540.htm)

Commercial insect repellents do not cloak the user in a chemical veil of protection. Any untreated exposed skin may be readily bitten by insects. Protection from both the nuisance and the health risks associated with insect bites is presently achieved by avoiding infested habitats, wearing protective clothing, and applying an insect repellent. As discussed below, such methods are unsatisfactory for a variety of reasons.

Current Insect Repellants

DEET

Currently marketed insect repellents fall into 2 categories: manufactured (chemical) repellents and natural (plant-derived) repellents. In general, the chemical repellents have a broader spectrum of efficacy and a greater duration of action than botanical repellents.

Commercial products include OFF!™, Cutter, Repel™, Sawyer™, Ben's™ (all in multiple formulations), and Ultrathon™. Registered for use by the general public since 1957, N, N-diethyl-3-methylbenzamide (previously called N, N-diethyl-m-toluamide), or DEET, remains the standard of currently available insect repellents. DEET, a broad-spectrum repellent, is effective against many species of crawling and flying insects, including mosquitoes, biting flies, midges, chiggers, fleas, and ticks.

The Environmental Protection Agency (EPA) estimates that about 30% of the US population uses a DEET-based product every year. Worldwide use exceeds 200 million people annually. Empirical testing of more than 20,000 other compounds over the last 45 years has not led to a more effective insect repellent than DEET being brought to market.

In the United States, DEET is sold in concentrations ranging from 5–40% and 100%. DEET is available in multiple formulations, including solutions, lotions, creams, gels, aerosol and pump sprays, and impregnated towelettes. EPA regulations require that the concentration of DEET in each product be disclosed on its label.

The 3M Company manufactures a polymer-based 33% DEET cream, called Ultrathon™, which is the standard issue repellent given to the US military. When tested under multiple environmental and climatic field conditions, Ultrathon™ was as effective as 75% DEET, providing up to 12 hours of greater than 95% protection against mosquito bites. Sawyer Products makes a controlled-release 20% DEET lotion, which traps the chemical in a protein particle that slowly releases it to the skin surface. This formulation provides a repellency equivalent to a standard 50% DEET preparation, lasting about 5 hours. Products with 5–35% DEET provide adequate protection under most conditions. However, the American Academy of Pediatrics recommends that DEET-containing repellents used on children should not contain more than 10% DEET. In addition, DEET containing insect repellants exhibit most of the drawbacks of chemical insect repellants discussed above.

Young children should not apply DEET-containing repellents themselves, to minimize the possibility of irritation of eyes or mucous membranes. Inadvertent exposure of such tissues to higher concentrations of DEET may result in pain, watering of the eyes, and general tissue irritation. For the same reasons, DEET should not be applied to a child's hands. To prevent irritation after the repellent is applied, it should be wiped from the palm surfaces to prevent inadvertent contact with the eyes, mouth, and genitals. The repellents should never be used on cuts, wounds, and inflamed, irritated, or eczematous skin. Aerosol formulations should not be inhaled or sprayed into the eyes. Contact with plastics (e.g., watch crystals, eyeglass frames), rayon, spandex, and painted or varnished surfaces should be avoided because DEET can damage those surfaces. Once indoors, the repellent-treated areas should be washed with soap and water. Washing the repellent from the skin surface is particularly important under circumstances where a repellent is likely to be applied for several consecutive days.

Repellents containing DEET must be carefully applied because they can damage plastics (such as watch crystals and eyeglasses frames), rayon, spandex, other synthetic fabrics, leather, and painted or varnished surfaces. DEET does not damage natural fibers, such as cotton or wool, and has no effect on nylon. There are many accounts of the unpleasant odor or greasy feel of DEET.

In children, concentrations greater than 10% of DEET, too frequent applications, and oral ingestion are associated with toxicity, including encephalopathy and seizures. Deaths have been documented in relation to improper exposure to DEET. DEET is not recommended for infants less than two month of age.

IR3535

IR3535 (3-[N-butyl-N-acetyl]-aminopropionic acid) is a chemical repellent that has been available in Europe for 20 years and has been sold in the United States since 1999. This repellent (at 7.5%) is currently available through the Avon Corporation as Skin-So-Soft Bug Guard Plus IR3535. IR3535 is structurally similar to the amino acid alanine, and the EPA classifies it as a biopesticide. It is labeled for use against mosquitoes, ticks, and biting flies. In a recent laboratory comparative study of the efficacy of insect repellents to prevent mosquito bites, Avon Corporation's IR3535-based repellent provided an average complete protection time of only about 23 minutes (range, 10–60 min) (Fradin, 2002).

Piperidine

Although not yet for sale in the United States, a piperidine-based repellent is sold in Europe as Autan Bayrepel. Derived from pepper, this repellent is labeled for use against ticks, mosquitoes, and flies. The manufacturer claims DEET-like efficacy against mosquitoes, lasting as few as 2 hr and sometimes as long as 8 hours, depending on the species.

Skin-So-Soft Bath Oil

Avon Corporation's Skin-So-Soft bath oil received considerable media attention several years ago when some consumers reported it to be effective as a mosquito repellent. Studies have shown that Skin-So-Soft bath oil has a minimal repellent effect, and it is at least 10 times less effective than 12.5% DEET. The limited mosquito repellent effect of Skin-So-Soft oil may be due to its fragrance or to other components of its formulation, which may possess some repellent activity. The manufacturer has never marketed the bath oil as an insect repellent.

Thousands of plants have been tested as sources of insect repellents. Although none of the plant-derived chemicals tested to date demonstrate the broad effectiveness and duration of the protection of DEET, a few appear to show repellent activity.

Citronella

Marketed products containing citronella include Natrapel™, Buzz Away™, Herbal Armor™, and Green Ban™. Oil of citronella is a plant-derived ingredient found in many natural or herbal insect repellents marketed in the United States. Oil of citronella is extracted from the grass plants *Cymbopogon nardus* and *Cymbopogon winterianus*. Conflicting data exist on the efficacy of citronella-based products. This data variation may be attributed to differences in study methodology, location, and species of the biting insects tested. One comparative laboratory study demonstrated that marketed citronella-based insect repellents protected against mosquito bites for an average of less than 20 minutes. In general, citronella-based repellents provide considerably shorter protection than DEET repellents. Therefore, they require more frequent reapplication to maintain their effectiveness. For maximum repellent effectiveness of these products, it is recommended to repeat applications at one-hour intervals.

Soybean Oil

This repellent may provide longer-lasting protection than citronella-based repellents. In some studies, one soybean oil product provided complete protection against mosquito bites for as long as 3.5 hours, and against blackflies for as long as 10 hours. However, the benefits of soybean oil as an insect repellent have not been extensively documented.

Eucalyptus

A derivative, p-menthane-3,8-diol (PMD), isolated from the oil of the lemon eucalyptus plant has shown promise as an insect repellent. A 30% PMD preparation appears to provide protection comparable to 20% DEET but requires more frequent reapplication to maintain the same level of protection. PMD-based repellents show low toxicity, but care must be taken to keep them out of the eyes because PMD can cause significant eye irritation.

A search for the perfect topical insect repellent has continued. The ideal agent would remain effective for at least 8 hours and have no toxic side effects. No available topical insect repellent meets those criteria.

There remains a need for an oral inhibitor of biting insects that would fulfill all of the criteria listed in Paragraph 0011 above. Such an agent would inhibit multiple species of biting arthropods, including but not limited to mosquitoes, remain effective for at least 8 hours, cause no irritation to the skin or mucous membranes, cause no systemic toxicity especially in children, be resistant to being rubbed or washed off and not have an unpleasant taste or smell.

SUMMARY

Certain embodiments of the present invention concern compositions and/or methods of producing and using biting insect inhibitors derived from naturally occurring products. In one aspect, an insect inhibitor composition suitable for human oral and/or topical application comprises one or more vitamins combined with one or more herbs. It will be understood that where the present disclosure refer to a composition comprising one or more herbs, the one or more herbs may be present in any form, including but not limited to the native herb, a crushed herb, an extract, a concentrate, a decoction, an infusion, a homogenate, an essence and/or a distillate of an herb.

In various embodiments, the compositions inhibit insects from biting subjects following oral ingestion of the compositions by the subjects. In other embodiments, the compositions reduce inflammation, swelling, redness and/or itching of the localized region of an insect bite. The compositions may be provided in any form known in the art, but in a preferred embodiment come in the form of a water-based solution suitable for administration with a spray bottle, for example by spraying into the mouth of a subject, followed by ingestion.

In another preferred embodiment, a composition suitable for human oral and/or external application comprises one or more vitamins combined with one or more herbs to inhibit mosquitoes from biting subjects.

A composition suitable for oral and/or external application may be provided in a variety of forms, including but not limited to a dilute liquid, a concentrated liquid, a more concentrated cream, a paste or a hydratable dry composition. Other possible forms may be solutions, lotions, creams, gels, aerosol and pump sprays, and impregnated towelettes. The composition may contain a variety of levels of the individual components. For example, a single application amount of the individual components of the composition may be determined. This amount may be administered as a single application or may be divided into multiple smaller applications dependent on the insect exposure and the individual. Where the composition is a liquid for oral application, for example, one squirt of a standard spray applicator may constitute one-fifth of a predetermined amount of the individual components, making five squirts the suitable application for an adult individual prior to insect exposure. Although dosage may vary, in certain embodiments a one fluid ounce spray applicator may contain enough liquid for about 250 sprays, making a 5-spray application about 1/50 of a fluid ounce.

The effective dosage of composition will depend upon a variety of factors known in the art, such as the body mass of the individual to whom the composition is administered, the relative sensitivities of different target insects to the composition and the length of exposure to insects. Where prolonged exposure may result in a decrease in efficacy, a repeated administration may be used.

Certain embodiments concern methods to minimize, inhibit and/or prevent insect bites. Other embodiments concern methods to treat a subject bitten by an insect. Such methods may comprise administering a composition suitable for oral and/or external application that includes at least one herbal compound combined with at least one vitamin compound. The composition may be administered in various forms as mentioned above. The amount of the individual components of the composition may be adjusted to provide an optimum insect inhibiting formulation, including a predetermined beneficial amount, such as several sprays for an adult subject and fewer for a young subject (e.g. an infant or child). The skilled artisan will realize that the disclosed methods include, but are not limited to administration to human subjects. However, subjects of interest may include humans, cats, dogs, horses, cows, goats, pigs, mammals and vertebrates in general. Where oral spray administration is inappropriate for administering to a particular species of mammal, alternative delivery methods may be utilized. For example, a standard dosage may be determined and mixed with a water and/or food supply for a subject animal. The skilled artisan will realize that with such administration the absorption of the composition may be affected by the type and/or amount of liquid or food ingested and dosages may be adjusted appropriately to compensate for reduced absorption.

In various embodiments, methods to treat subjects for insect bites may comprise oral and/or topical administration of a composition comprising at least one vitamin and at least one herb. The administration may be used to reduce, inhibit

or eliminate localized swelling, itching, inflammation, redness and other reactions to insect bites.

DETAILED DESCRIPTION

Definitions

As used herein, the term "about" means plus or minus 15 percent of an amount. For example, "about 100" would mean a value between 85 and 115. As used herein, the terms "a", "an" and "the" may refer to one or more than one of an item. The terms "and" and "or" may be used in the conjunctive or disjunctive and will generally be understood to be equivalent to "and/or".

As used herein, an "inhibitor" of biting insects or "biting insect inhibitor" refers to a composition that reduces the number of insect bites suffered by a subject after administration of the composition, in comparison to a control subject exposed to insects under identical circumstances without administration of the composition. It will be understood that an "inhibitor" of biting insects may or may not also repel insects, that is prevent insects from landing on a subject. In preferred embodiments, the composition is effective to completely inhibit biting insects, i.e., the subject suffers no insect bites after administration of the composition. However, the skilled artisan will realize that efficacy of insect inhibitors may depend upon a variety of factors; such as the dosage of inhibitor administered, the route of administration (for example, oral or topical); the length of time following administration; the body mass of the subject; the number and species of biting insects present; and potentially environmental factors such as humidity, temperature, wind speed, sunlight or shade, etc.

Description

The following embodiments relate to compositions that, in one aspect, inhibit insects from biting subjects following oral administration to the subjects. The compositions provide prolonged protection of subjects against biting insects. The subjects may be adult subjects, juvenile subjects and/or infant subjects. Because the compositions exhibit little or no toxicity, they may be administered to infant subjects to protect against biting insects, unlike present commercial insect repellants that are not recommended for use with infants.

Plants whose essential oils reportedly have purported insect repellent activity include citronella, cedar, verbena, pennyroyal, geranium, lavender, pine, cajeput, cinnamon, rosemary, basil, thyme, allspice, garlic, and peppermint. Unlike synthetic insect repellents, plant-derived insect repellents have been poorly studied. When tested, most of the essential oils yield short-lasting protection, lasting from a few minutes to as long as 2 hours. The use of plant derived materials as inhibitors of insect biting remains uncharacterized to date.

Embodiments relate to compositions and the use of these compositions as agents for the prevention and/or treatment of insect bites. The compositions may include combinations or sub-combinations of components derived from one or more vitamins such as thiamin (B-1), riboflavin (B-2), niacin (B-3), pantothenic acid (B-5), pyridoxine (B-6), folic acid (B-9), cyanocobalamin (B-12), choline, inositol, d-biotin, para-aminobenzoic acid, lecithin and one or more herbs such as peppermint, barley grass, lobelia, chlorella, watercress, alfalfa, parsley and rice bran. In one embodiment, the composition may comprise a suitable amount of all the herbs and all the vitamins mentioned.

In one embodiment, the composition is administered to an individual in need of treatment to reduce inflammation (e.g. orally administered and/or externally applied to an insect bite). In another embodiment, the composition may be administered to an individual to inhibit biting insects. In still another embodiment, the compositions may be administered to maintain a continuous protection against biting insects for a prolonged period (e.g. approximately 8 hours).

The following information is presented as general background information relevant to various herbs and vitamins. The herbs discussed below have been reported to have effects as naturopathic and/or homeopathic remedies for a variety of conditions. The skilled artisan will realize that such naturopathic and/or homeopathic uses may or may not be relevant to the compositions and methods disclosed herein for inhibition of biting insects and/or inflammation caused by insect bites.

Herbs

Barley: *Hordeum distichon* (LINN.), *Hordeum vulgare* L.; Graminaceae

Action and Uses: Pearl Barley may be used for the preparation of a decoction which is a nutritive and demulcent drink in febrile conditions and in catarrhal affections of the respiratory and urinary organs. Barley water is used to dilute cows' milk for young infants, reportedly to prevent the formation of hard masses of curd in the stomach. Malt is produced from barley by a process of steeping and drying that develop a ferment 'diatase' needed for the production of alcoholic malt liquors, but in the form of Malt Extract it is largely used in homeopathic medicine. Vinegar is an acid liquid produced by oxidation of fermented malt wort. Malt vinegar is the only vinegar that has been used medicinally. The parts of the barley plant usually used include grain and germinated seeds (barley sprouts). Reported properties include demulcent, digestant, carminative, nutritive.

Uses: A mucilaginous substance is obtained when hulled barley (pearl barley) is cooked. It is thought to be a good nutritional source for throat or stomach problems. The demulcent properties of cooked barley may be useful in external treatment of sores, fevers, diarrhea, gout, and tumors. Used as a tonic during convalescence. Barley water is a skin freshener, cleanses and softens skin. Drinking barley water is reported to clear and beautify the skin; sweeten with honey and orange juice.

Nutrient Content: Iron, sulfur, phosphorus, magnesium, niacin, protein, vitamin B1. Barley shoots are reportedly used to dry breast milk, treat food stagnation, weak stomach, weak digestion, loss of appetite, and hepatitis.

Warning: Barley should be avoided by nursing mothers.

Lobelia: Lobelia inflata (LINN.) Family: N.O. Lobeliaceae

Action and Uses: Some reported uses are as an expectorant, diaphoretic, and anti-asthmatic. It should not be employed as an emetic. Some reports indicate value as an expectorant in bronchitis or as a counterirritant when combined with other ingredients in ointment form. It is sometimes given in convulsive and inflammatory disorders such as epilepsy, tetanus, diphtheria and tonsilitis. It may also be used for relaxation purposes. It may also be used as an enema.

Externally, an infusion has been found useful in ophthalmia, and an ointment may be used as a local application for sprains, bruises, or skin diseases, alone or in powder combined with other components. The oil of *Lobelia* is reportedly of use in treating tetanus. The oil may be useful

as an expectorant, nauseant, sedative, and diaphoretic, when given every one or two hours. In excessive doses the effects may include depression, nausea, cold-sweats, and possibly death.

Other Species—*L. Dortmanna* is indigenous to Great Britain, and is similar in action to *L. inflata*. A dose of the fresh plant reportedly cures headaches and noises in the ears. *L. Erinus*. A dose of the plant has reportedly been used in cancer and has produced pain relief. It has also been used as to treat syphilis. *LOBELIA,* BLUE (*L. Syphilitica*) and *LOBELIA* RED (*L. Cardinalia*). Both of these are used in homeopathy. The first is diaphoretic, emetic and cathartic and has been used in dropsy, diarrhea, syphilis and dysentery, the root being the part used. The Red *Lobelia* is said to be anthelmintic, nervine and antispasmodic. *L. Kalmit.* is said to be used by the Indians in the cure of syphilis. *L. purpurascens*. also has reported homeopathic medicinal uses.

Watercress: *Nasturtium officinale.* Family: N.O. Cruciferae

Action and Uses: Watercress is reportedly of use for its antiscorbutic qualities and has been used as such from the earliest times. As a salad it supposedly promotes appetite. Watercress has also reportedly been used in tuberculosis. Its active components are said to be at their best when the plant is flowering. Reported properties include diuretic, expectorant, purgative, stimulant, stomach aid, and tonic.

Reportedly good for urinary bladder problems. Promotes kidney function and relieves fluid retention. Relieves indigestion and stops gas formation. Stimulates rate of metabolism and is taken as a spring tonic. Watercress has reportedly been recommended for use against gout, scurvy, mild digestive disturbances, anemia, and catarrh of the upper respiratory tract. Reportedly effective as an expectorant, it is also beneficial for tuberculosis, scurvy, anemia, and eczema. Its high vitamin C content makes it a good general preventative. Used as a post-partum (after childbirth) remedy to prevent infections. Having a slight iodine content, watercress is a dietary remedy for thyroid problems. In addition, the richness of its mineral, iron and iodine content stimulates glandular activity. Limited loss of hair caused by a fungus may be treated by an application of watercress juice. Leaf extracts are used clinically in India to correct vitamin deficiency.

Dosage: As an expressed juice; 1 to 2 fluid ounces.

Nutrient Content: Iodine, niacin, magnesium, manganese, phosphorus, sodium, iron, calcium, vitamins A, B1, B2, C, E and zinc.

Warning: Do not harvest leaves from polluted waters. Poisonings have resulted from eating leaves from plants growing in polluted waters, from which the plant has absorbed heavy metals and toxins. Excessive or prolonged use can lead to stomach upset and kidney problems. It should not be taken daily and no longer than 4 weeks even with interruptions. The juice should not be taken undiluted, because it can produce inflammations in the throat and stomach. Some doctors caution against use during pregnancy.

Parsley: *Carum petroselinum* (BENTH.) Family: N.O. Umbelliferae

Action and Uses: The leaves are extensively cultivated, not only for use fresh, but also for the purpose of being dried and powdered. In addition to the leaves, the stems are also dried and powdered. The roots of the turnip-rooted variety are used as a vegetable and flavoring. Two-year-old roots and dried leaves are employed for making Parsley Tea. The seeds are used for the extraction of an oil called Apiol. The best kind of seed for homeopathic or naturopathic medicinal purposes is that obtained from the Triple Moss curled variety.

The oleoresin of parsley has been reported to influence nerve centers of the head and spine, and in large doses may produces giddiness and deafness, decreased blood-pressure and slowing of the pulse and possibly paralysis. Parsley is reportedly used chiefly for its diuretic properties, a strong decoction of the root being used to treat the kidneys, (dropsy and jaundice). The dried leaves are also used for the same purpose.

A report in France indicated a popular remedy for scrofulous swellings is green Parsley and snails, pounded in a mortar to an ointment, spread on linen and applied daily. The bruised leaves, applied externally, have been used in a similar manner as Violet leaves (also Celandine, Clover and Comfrey), to treat tumors suspected to be of a pre-cancerous nature. It is also reported that this may be a remedy for the bites and stings of poisonous insects.

Peppermint: *Mentha piperita* (SM.). Family: N.O. Labiatae. Synonym—Brandy Mint.

Action and Uses: The parts of the herb used include the leaves, oil and flowering tops. Peppermint oil is the most extensively used of all the volatile oils. The anti-spasmodic action of the volatile oil is more marked than in any other oil, and is reported to relieve pains arising in the alimentary canal.

From its stimulating, stomachic and carminative properties, it is used in certain forms of dyspepsia, being mostly used for flatulence and colic. It may also be employed for other sudden pains and for cramp in the abdomen. Wide use has been made of Peppermint in cholera and diarrhea. May be used for chills, colic, fever, nausea, diarrhea, heart trouble, rheumatism, convulsions, spasms, dizziness, vomiting, travel sickness, dysentery, cholera, dysmenorrhea, palpitations of the heart, the grippe, hysteria, insomnia, neuralgia, and also reportedly used for headaches. Used for colds, flu, sore throat, laryngitis, gas and mild digestive disorders. The leaves can be made into a salve or a bath additive for itching skin conditions. Extracts have been used against herpes simplex, Newcastle disease, and other viruses. The oil reportedly stops spasms of smooth muscles. Externally, peppermint helps rheumatism, neuralgia, and headaches (e.g., migraines).

Reportedly, it is generally combined with other medicines when its stomach aiding effects are required, being also employed with purgatives to prevent griping. Oil of Peppermint reportedly alleviates sickness and nausea, and is used to disguise the taste of unpalatable drugs, as it imparts its aromatic characteristics to whatever prescription it enters into. It is also reportedly used as an infants' cordial. The oil itself is often combined with sugar and added to pills, also a spirit made from the oil, but the preparation in most general use is Peppermint Water, which is the oil and water distilled together.

Peppermint is reportedly used to assist in raising internal heat and inducing perspiration, although its strength is soon exhausted. In slight colds or early indications of disease, a free use of Peppermint tea may treat the disease onset. Peppermint tea is used also for palpitation of the heart. In cases of hysteria and nervous disorders, Peppermint was reported to be augmented by the addition of equal quantities of Wood Betony.

A single cup of peppermint tea, drunk in sips as hot as warm as possible, may be of use to treat for example queasiness, nausea, a feeling of fullness, or severe vomiting. Peppermint

tea promotes bile flow, improves bile production in the liver, and also exercises a positive influence on pancreatic function. But, avoid peppermint if internal ulcers are present.

Warning: May interfere with iron absorption. Oil is toxic if taken internally in large doses; may cause dermatitis. Menthol, the major chemical component of peppermint oil, may cause allergic reactions. Avoid prolonged use of the essential oil as an inhalant. Mint should not be given to children for more than a week at a time without a break. It is advised not to give any form of mint directly to young babies. Also, peppermint may reduce milk flow if breast-feeding.

Alfalfa: *Medicago sativa* L. Leguminosae

Uses: Alfalfa tea is commonly used as a beverage. Nutritious fresh or dried leaf tea is reportedly used to promote appetite, for weight gain, as a diuretic, and reportedly stops bleeding. It is a source of commercial chlorophyll and carotene. It also contains the anti-oxidant tricin. Alfalfa has anti-fungal, and setrogenic activity. Unsubstantiated claims include use for cancer, diabetes, alcoholism, arthritis, etc. It is high in chlorophyll and nutrients. It is reported to alkalinize the body, as well as detoxify the body, especially the liver. It is reportedly used for colon disorders, anemia, hemorrhaging, indigestion, vitamin or mineral deficiency, laxative, cystitis, blood purifier, gas, edema, diabetes, ulcers, and arthritis. It may promote pituitary gland function. Effects include alterative, antipyretic, diuretic, appetite stimulant and hemostatic effects.

Nutrient Content: It contains biotin, calcium, choline, inositol, iron, magnesium, PABA, phosphorus, potassium, protein, sodium, sulfur, tryptophan (amino acid), and vitamins A, B complex, C, D, E, K, P, and U.

Warning: Alfalfa has been reported to aggravate lupus and other auto-immune disorders. Avoid alfalfa if an auto-immune problem exists. Consuming large quantities of Alfalfa saponins may cause breakdown of red blood cells, causing bloating in livestock (thus weight gain). Recent reports suggest that Alfalfa sprouts (or the canavanine, especially in the seeds), may be associated with lupus (systemic lupus erythematosus), causing recurrence in patients in which the disease had become dormant.

Rice Bran

Rice bran is a by-product of the milling of rice. It consists mostly of the bran layer and germ of the rice with some fragments of hull and broken rice. The calcium level in rice bran will vary with the amount of added calcium carbonate. When the amount of added calcium carbonate exceeds 3 percent (total calcium exceeds 1.2 percent), then the percentage of calcium carbonate must be stated in the product name. Rice bran is similar to oats in crude protein, fat, fiber and energy.

Rice Bran is a source of original B-complex in the outer layers of the rice grain. Vitamin B-complex is a source for strong, steady nerves and sustained energy. The B-complex has been reportedly used for cessation from aggravation. Rice Bran, being a very rich source of a balanced B-complex profile of vitamins, can be used to maintain normal blood sugar levels for those suffering from low blood sugar.

Chlorella

A genus of unicellular green algae, potentially a source of high-grade protein and B-complex vitamins. Any alga of the genus *Chlorella*. The name *Chlorella* derives from the Latin words meaning 'leaf' (green) and 'small', referring to the unusually high content of chlorophyll (the highest of any known plant) that gives *Chlorella* its characteristic deep emerald-green color. This particular fresh-water, single celled microscopic plant contains a host of nutrients. In addition to chlorophyll it contains vitamins, minerals, dietary fiber, nucleic acids, amino acids, enzymes, CGF (*Chlorella* Growth Factor) and other substances. Under favorable growth conditions of strong sunlight, pure water and clean air, *Chlorella* multiplies at an incredible rate, the complete reproduction cycle taking less than 24 hours.

There are over 70,000 species of algae in the world. *Chlorella Pyrensoida* is one of the most common species found in watersheds. *Chlorella* contains the full Vitamin B Complex, Vitamins E & C and has a wide range of minerals, including magnesium, potassium, iron and calcium.

Uses. Reportedly of use for treatment of cancer. May increase production of T-cells and macrophages with activity against cancer. *Chlorella* has reportedly been shown to promote the production of interferon (IFN), which stimulates macrophage production. Chlorella may stimulate the activity of T-cells and macrophages by increasing IFN levels thus enhancing the immune system's ability to combat infection, cancer and other diseases.

Chlorella has the highest amounts of chlorophyll of any plant known. Chlorophyll is structurally similar to hemoglobin (found in red blood cells) except for containing magnesium instead of iron. Magnesium is essential for the heart to function properly. Chlorophyll has reportedly been used in the treatment of cardiac hypertension. Chlorophyll has also been used to treat anemia and reportedly stimulates the production of red blood cells in the body.

When eaten, *Chlorella* reportedly causes beneficial stomach bacteria (Lactobacillus) to multiply at four times the normal rate. This improves digestion and thus the body's ability to absorb nutrients.

Chlorella includes a fibrous, indigestible outer shell (20%) and inner nutrients (80%). It is the fibrous material that has been reported to bind with heavy metals and other toxins that may accumulate in the bodies. It is reported that a period of 3–6 months consumption of *Chlorella* may result in elimination of heavy metals and other toxins. Use of up to 15–20 grams of *Chlorella* per day has been reported.

Chlorella has been used for treatment of Alzheimer's Dementia and Attention Deficit Disorder. Alzheimer's patients have been demonstrated to have high levels of aluminum in their brains. *Chlorella* may assist in elimination of aluminum and may also improve oxygen transfer capabilities, aiding alertness and mental focus.

Chlorella has the ability to quadruple in quantity every 20 hours, which is an extraordinarily high growth rate. Exactly what CGF (*Chorella* growth factor) is remains a mystery. CGF has hormone-like qualities and appears to stimulate tissue repair. *Chlorella* has been used as a topical treatment for damaged tissue.

Poor diet, for example the consumption of excess carbonated soft drinks and processed sugars, may result in blood acidification. *Chlorella* is alkaline in nature any may help balance this acidity to maintain a neutral blood pH, optimally 7.4. *Chlorella* has a number of properties which are helpful to organs and tissues that have been injured by a variety of causes. It has been reported to promote liver health. Although some positive effects of taking *Chlorella* may be felt immediately, such as correcting constipation and bad breath, *Chlorella*'s full nutritive and detoxifying capabilities often take 3–6 months to be fully appreciated. *Chlorella* belongs to a small group of foods that have been called Nutriceuticals.

Both Watershed *Chlorella* and Watershed *spirulina* are particular strains of algae. Watershed *Chlorella* is a strain of

algae known as *Chlorella Pyrensoida*. From a single pure source, this algae has been reproduced for thousands of generations. Control of the genetic purity of Watershed *Chlorella* may provide beneficial effects on its nutritional and nutriceutical properties.

It has been reported that mice injected with cancer cells showed a higher resistance to this challenge if they had been fed *Chlorella*. Other tests reported that *Chlorella* growth factor improves resistance to abdominal tumors while increasing the number of immune cells in the abdominal cavity. *Chlorella* promotes cell reproduction, reduces cholesterol and increases hemoglobin levels. Because of its broad nutritional and detoxifying profile, *Chlorella* promotes the repair of bodily organs and tissues that have been injured or otherwise damaged.

Numerous research projects in the USA and Europe indicate that *Chlorella* can also aid the body in the breakdown of persistent hydrocarbon and metallic toxins such as DDT, PCB, mercury, cadmium and lead, while strengthening the immune system response. In Japan, interest in *Chlorella* has focused largely on its detoxifying properties, its ability to neutralize or remove poisonous substances from the body. The fibrous materials in *Chlorella* also improve digestion and promote the growth of beneficial aerobic bacteria in the stomach.

Analysis shows that *Chlorella Pyrensoidosa* contains a comparable variety of minerals, vitamins and amino acids to other algae: Sporopollenin, which is only present in *Chlorella Pyrensoida*, acts in the same detoxifying way. *Chlorella*'s indigestible cell wall needs to be ruptured to allow access to its nutrients and a variety of methods are used, some of which damage the nutrients.

The method used herein by the *Chlorella* producer (TCMC) ensures the highest quality, which is confirmed by an annual independent analysis by the Japan Food Research Laboratory. Japan is the only country that has strict standards and importation controls over heavy metals and bacterial content in *Chlorella*. The digestibility of the *Chlorella* used is confirmed by the Japan Government's Ministry of Health to be between 76% and 79%, the highest on the market. *Chlorella* was analyzed by Dr L. Lewis, Doctor of Physiology at Duke University in 1992. Using a Scanning Electron Microscope (SEM), two samples of *Chlorella* were examined, the source used herein and a competitor's brand. Both were deemed to be free of contamination, however, the source of *Chlorella* used herein was the only one found to have a disrupted cell wall by SEM examination.

Additive: Potassium Sorbate

In certain embodiments, a preservative may be added to a composition of insect inhibitor to prevent growth of microorganisms and/or to maintain freshness. One example of a preservative is potassium sorbate.

Potassium sorbate is a potassium salt of sorbic acid, a polyunsaturated fat used to inhibit mold growth. Sorbic acid was first isolated from the oil of the unripened rowan berry (sorbapple or mountain ash berry) in 1959 by A. W. Hoffmann. Sorbic acid obtained its name from the scientific name for mountain ash (i.e. *Sorbus aucuparia*, Linne), the parent of the rowan berry. The value of sorbic acid, or its salts, was not immediately recognized. It was only much later that these compounds were appreciated for their ability to interfere with ATP metabolism in microbes, while posing no health risk when consumed by mammals. Sorbic acid is one of the most thoroughly tested food additives in history. It has been found to be non-toxic even when taken in large quantities, and breaks down in the body into water and carbon dioxide in the Kreb Cycle.

Herbal therapies may be considered a form of combination therapy. The collective effect of these agents typically results in reduced toxicity, and appearance of new and novel activities.

Vitamins

In various embodiments, the compositions disclosed herein comprise one or more vitamins. The following discussion provides general background information on vitamins.

Choline

Reportedly important in controlling fat and cholesterol buildup in the body; prevents fat from accumulating in the liver; facilitates the movement of fats in the cells; helps regulate the kidneys, liver and gallbladder; important for nerve transmission; helps improve memory.

Deficiency Symptoms: Reportedly a deficiency may result in cirrhosis and fatty degeneration of the liver, hardening of the arteries, heart problems, high blood pressure and hemorrhaging kidneys. Choline reportedly assists in controlling weight as well as cholesterol levels, keeping cell membranes healthy and in preventing gallstones. It is thought to be useful in the maintenance of the nervous system, assisting memory and learning, and may help to fight infections, including hepatitis and AIDS. Choline is reportedly needed for normal membrane structure and function.

Choline is the major precursor of betaine, and it is used by the kidneys to maintain water balance and by the liver as a source of methyl-groups for methionine formation. It is also used to produce the important neurotransmitter acetylcholine. It assists in nerve impulse transmission, gallbladder regulation, liver functions and lecithin production.

A deficiency of choline does not happen easily but if it is deficient it may lead to liver disease, raised cholesterol levels, high blood pressure as well as kidney problems. Choline deficiency may also manifest itself in the inability to digest fats, stunted growth and fatty buildup in the liver. Memory and brain function may also be impaired.

Dosage: The dosage indicated is the Recommended Dietary Allowance (RDA), but is the minimum required per day, to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually increased considerably, but the toxicity level must be kept in mind. The dosage is relative to the amount of fats ingested in the diet, but for a guide: male 550 mg/per day and female 425 mg per day, although mega dose vitamin proponents use far higher dosages. More choline may be required during alcohol consumption, refined sugar consumption or taking large amounts of nicotinic acid.

Toxicity and Symptoms of High Intake: The maximum level of choline has been set for safety at 3.5 g/day. Taking too much choline could result in nausea, depression, and could trigger existing epilepsy. Hypotension, sweating, salivation and diarrhea have also been reported. Choline is recommended in the same dose as inositol and together with the B group vitamins as well as vitamin A and linoleic acid.

Vitamin B-1 (Thiamin)

Vitamin B-1 reportedly plays a role in the body's metabolic cycle for generating energy, aids in the digestion of carbohydrates and is important for the normal functioning of the nervous system, muscles and heart. It also stabilizes the appetite, promotes growth and good muscle tone.

Deficiency Symptoms: May lead to the loss of appetite, weakness and feeling tired, paralysis and nervous irritability, insomnia, loss of weight, aches and pains, mental depression and constipation, heart and gastrointestinal problems.

Vitamin B1 reportedly is used in many different body functions and deficiencies may have far reaching effects on the body. Yet very little of this vitamin is stored in the body, and depletion of this vitamin can happen within 14 days. Thiamin is also an essential nutrient, somebody suffering from beriberi, scarcely able to lift their head from their pillow, will respond quickly from injected thiamin, and will be on their feet within a matter of hours.

Vitamin B1 may enhance circulation, help with blood formation and the metabolism of carbohydrates. It is also needed for the health of the nervous system and is used in the biosynthesis of a number of cell constituents, including the neurotransmitter acetylcholine and gamma-aminobutyric acid (GABA). It is used in the manufacture of hydrochloric acid, and therefore plays a part in digestion.

It is also good for the brain and may help with depression and assist with memory and learning. In children it is required for growth and additionally it has shown some indication to alleviate arthritis, cataracts and aid in infertility.

Dosage: The Recommended Dietary Allowance (RDA) is the minimum required per day to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually increased considerably, but the toxicity level must be kept in mind. For males: 1.4 mg per day and females: 1.0 mg per day, although 50 mg is usually used in supplementation.

Inositol

Necessary for the formation of lecithin; aids in the breakdown of fats; helps reduce blood cholesterol; helps prevent thinning hair.

Deficiency Symptoms: May result in high blood cholesterol, constipation, eczema, or hair loss. Inositol is needed for health at the cellular level and a fair concentration is found in the lens of the human eye as well as the heart. Inositol plays an important part in the health of cell membranes especially the specialized cells in the brain, bone marrow, eyes and intestines. Inositol is said to promote healthy hair, hair growth, and helps in controlling estrogen levels and may assist in preventing breast lumps. It may also be of benefit in reducing blood cholesterol levels.

Dosage: The RDA is the minimum required to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually increased considerably, but the toxicity level must be kept in mind. Supplementation is usually 100 mg per day

Toxicity and Symptoms of High Intake: No toxic effects known, but diarrhea has been noted with the intake of very high dosage of inositol.

Folic Acid (Vitamin B-9)

Folic acid, also known as Vitamin B9, is also referred to as folacin or folate. This vitamin can be manufactured by the body and stored in the liver. It is needed for DNA and RNA synthesis, essential to the formation of red blood cells by its action on the bone marrow; aids in amino acid metabolism.

Deficiency Symptoms: A deficiency of folic acid in an unborn baby may increase the risk of the baby being born with spina bifida and other serious defects of the nervous system. Deficiency of folic acid may lead to fatigue, acne, a sore tongue, cracking at the corners the mouth (same as deficiency of vitamin B2, vitamin B6 as well as iron). Long term deficiency may result in anemia and later in osteoporosis, as well as cancer of the bowel and cervix.

Folic acid is reportedly needed for DNA synthesis and cell growth and is important for red blood cell formation, energy production as well as the forming of amino acids. Folic acid is essential for creating heme, the iron containing substance in hemoglobin, crucial for oxygen transport. It is important for cell division and replication. It is also required for protein metabolism and in treating folic acid anemia. This nutrient may be effective in treating depression and anxiety. Folic acid is reportedly very important in the development of the nervous system of a developing fetus.

Dosage: The dosage (400 micrograms per day) is the Recommended Dietary Allowance (RDA). In the therapeutic use of this nutrient, the dosage is usually increased considerably.

Pregnant women are sometimes advised to take a small supplement of folic acid to help prevent spina bifida and other congenial nervous disorders, and it may also reduce the risk of toxemia in pregnancy, premature labor and hemorrhaging. It is also thought to enhance the production of milk after delivery. Sufferers of psoriasis may consider taking extra folic acid, people under stress or anyone consuming alcohol. Women on birth control pills or hormone replacement therapy may benefit from folic acid. Light, heat and storage for extended periods can destroy this vitamin. Localized deficiencies may exist for smokers, as low levels have been detected in the lungs of smokers.

Toxicity and Symptoms of High Intake: Those on medication for epilepsy should be careful with large amounts of folic acid, since it can change the functioning of such drugs. Too much folic acid may mask a Vitamin B12 deficiency. Regular high intake of folic acid may cause digestive upset, energy loss and insomnia. Folic acid is more effective when taken with the B group vitamins—especially vitamin B12 and vitamin B6. Vitamin C is also recommended.

Vitamin B5—Pantothenic Acid

Participates in the release of energy from carbohydrates, fats and protein, aids in the utilization of vitamins; improves the body's resistance to stress; helps in cell building and the development of the central nervous system; helps the adrenal glands, fights infections by building antibodies.

Deficiency Symptoms: May lead to skin abnormalities, retarded growth, dizzy spells, digestive disturbances, vomiting, restlessness, stomach stress, muscle cramps. Consequences of low levels include frequent infection, fatigue, abdominal pains, sleep disturbances and neurological disorders including numbness, paresthesia (abnormal sensation such as "burning feet" syndrome), muscle weakness and cramps are also possible indications that this nutrient is in short supply.

Vitamin B5 plays an important role in the secretion of hormones, such as cortisone. Pantothenic acid is also used in the release of energy as well as the metabolism of fat, protein and carbohydrates. It is used in the creation of lipids, neurotransmitters, steroid hormones and hemoglobin.

Dosage: Recommended dosage of 10–100 mg is indicated.

Toxicity and Symptoms of High Intake: Pantothenic acid does not appear to be toxic in high dosage, although diarrhea, digestive disturbances and water retention have been reported on dosage exceeding 10 g a day.

Vitamin B-2 (Riboflavin)

Necessary for carbohydrate, fat and protein metabolism; aids in the formation of antibodies and red blood cells;

maintains cell respiration; needed for the maintenance of good vision, skin, nails & hair; alleviates eye fatigue; promotes general health.

Riboflavin is manufactured in the body by the intestinal flora and is easily absorbed, although very small quantities are stored, so there is a constant need for this vitamin. It is required by the body to use oxygen and for the metabolism of amino acids, fatty acids, and carbohydrates. Riboflavin is further needed to activate vitamin B6 (pyridoxine), helps to create niacin and assists the adrenal gland. It may be used for red blood cell formation, antibody production, cell respiration, and growth.

It eases watery eye fatigue and may be helpful in the prevention and treatment of cataracts. Vitamin B2 is required for the health of the mucus membranes in the digestive tract and helps with the absorption of iron and vitamin B6. Although it is needed for periods of rapid growth, it is also needed when protein intake is high.

Deficiency Symptoms: May result in itching and burning eyes; cracks and sores in the mouth and lips; bloodshot eyes; purplish tongue; dermatitis; retarded growth; digestive disturbances; trembling; and sluggishness. A shortage of this vitamin may manifest itself as eye disorders, inflammation of the mouth and tongue, and skin lesions. Dermatitis, dizziness, hair loss, insomnia, light sensitivity, poor digestion, retarded growth, and slow mental responses have also been reported. Burning feet can also be indicative of a shortage of B2.

Dosage: The RDA is the minimum that required per day to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually increased considerably, but the toxicity level must be kept in mind. Male 1.6 mg per day and female 1.2 mg per day although 50 mg is mostly recommended for supplementation. Extra dosage might be needed when consuming alcohol, antibiotics, and birth control pills or doing strenuous exercise, under stress or on a calorie-restricted diet.

Toxicity and Symptoms of High Intake: The limited capacity to absorb orally administered riboflavin precludes its potential for harm. Riboflavin intake of many times the RDA is without demonstrable toxicity. A yellow discoloration of the urine is seen with an increased intake of this vitamin.

Niacinamide (Niacin—Vitamin B-3)

Niacin is derived from two compounds—nicotinic acid and niacinamide. It improves circulation and reduces the cholesterol level in the blood; maintains the nervous system; helps metabolize protein, sugar and fat; reduces high blood pressure; increases energy through proper utilization of food; prevents pellagra; helps maintain a healthy skin, tongue and digestive system.

Vitamin B3 is required for cell respiration, helps in the release of energy and metabolism of carbohydrates, fats, and proteins, proper circulation and healthy skin, functioning of the nervous system, and normal secretion of bile and stomach fluids. It is used in the synthesis of sex hormones, treating schizophrenia and other mental illnesses, and as a memory-enhancer.

Nicotinic acid (but not nicotinamide) given in drug dosage reportedly improves the blood cholesterol profile, and has been used to clear the body of organic poisons, such as certain insecticides. People report more mental alertness when this vitamin is in sufficient supply. Niacin is best taken with the B group vitamins and vitamin C.

Deficiency Symptoms: May result in pellagra, gastrointestinal disturbance, nervousness, headaches, fatigue, mental depression, vague aches and pains, irritability, loss of appetite, insomnia, skin disorders, muscular weakness, indigestion, and canker sores.

Dosage: The RDA is the minimum that required per day to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually increased considerably, but the toxicity level must be kept in mind. Male 18 mg per day and female 13 mg per day although 100 mg is mostly used in supplementation.

Large doses given to lower cholesterol may produce hyperuricemia, and hepatic abnormalities. These effects are reversed if the drug is reduced in amount or discontinued. People with diabetes, glaucoma, any liver disease or peptic ulcers should be careful of niacin supplementation. Your daily cup of coffee also provides about 3 milligrams of niacin

Toxicity and Symptoms of High Intake: Nicotinic acid, but not nicotinamide in doses larger than 200 mg causes flushing by dilating the blood vessels, which can also cause the blood pressure to drop. These flushes are normally harmless. Large dosages can also cause itching, elevated blood glucose, peptic ulcers and liver damage.

Vitamin B-6 (Pyridoxine)

Necessary for the synthesis and breakdown of amino acids; aids in fat and carbohydrate metabolism; aids in the formation of antibodies; maintains the central nervous system; aids in the removal of excess fluid of premenstrual women; promotes healthy skin; reduces muscle spasms, leg cramps, hand numbness, nausea & stiffness of hands; helps maintain a proper balance of sodium & phosphorous in the body.

Pyridoxine is required for the balancing of hormonal changes in women as well as assisting the immune system and the growth of new cells. It is also used in the processing and metabolism of proteins, fats and carbohydrates. Pyridoxine reportedly may also be of benefit for children with learning difficulties, as well as assisting in the prevention of dandruff, eczema and psoriasis.

Pyridoxine should be taken together with the entire B group vitamins, and in supplementation the quantity of B6 should be nearly the same as B2, as the B2 is needed to activate the Pyridoxine. Vitamin C, magnesium, sodium, potassium, zinc, linoleic acid and fatty acids may also be used in combination.

Deficiency Symptoms: May result in nervousness, insomnia, skin eruptions, loss of muscular control, anemia, mouth disorders, muscular weakness, dermatitis, arm and leg cramps, loss of hair, slow learning, and water retention. Irritability, nervousness and insomnia as well as general weakness, skin changes such as dermatitis and acne as well as asthma and allergies might develop when pyridoxine is in short supply. Symptoms may include nails that are ridged, an inflamed tongue as well as changes to bones—which can include osteoporosis and arthritis. Kidney stones may also appear. Women in particular may suffer from premenstrual fluid retention, severe period pains, emotional PMS symptoms, premenstrual acne and nausea in early pregnancy. Mood swings, depression as well as loss of sexual drive is sometimes noted when pyridoxine is in short supply and the person is on hormone replacement therapy or on birth control pills. Symptoms will be very much like those of B2 and B3 deficiency. Vitamin B6 is needed by the body to manufacture its own B3 vitamin.

Dosage: The RDA is the minimum that required per day to ward off serious deficiency of this particular nutrient. In the therapeutic use of this nutrient, the dosage is usually

increased considerably, but the toxicity level must be kept in mind. Males 2 mg per day and females 2 mg per day. More may be required if taking antidepressants, contraceptive pills or on hormone replacement therapy. As this vitamin is readily lost in the urine, it must be taken regularly to ensure an adequate amount in the body. A very high protein diet, alcohol use, or allergies to MSG (mono sodium glutamate) and/or tartrazine may also indicate a need for increased vitamin B6 intake.

Toxicity and Symptoms of High Intake: Supplementation should be controlled as extreme dosage, such as in excess of 2,000 mg per day, may cause neurological damage. People on medication for Parkinson's disease should be careful about taking Vitamin B6 as it can inactivate L-dopa. People taking pyridoxine late at night sometimes experience very vivid dreams.

Biotin

Aids in the utilization of protein, folic acid, Pantothenic acid, and Vitamin B-12. Biotin is used in cell growth, the production of fatty acids, metabolism of fats, and proteins. It plays a role in the Kreb cycle, which is the process in which energy is released from food. Biotin is also indicated for healthy hair and skin, sweat glands, nerve tissue, bone marrow, and assisting with muscle pain. Biotin also helps with the transfer of carbon dioxide. Biotin is useful for maintaining a steady blood sugar level.

Biotin should be taken with the B-group vitamins, but Vitamin C, Vitamin B5 (pantothenic acid), Vitamin B12 and sulfur are good adjuvants. Biotin is sometimes added to the diet of a patient suffering from alopecia, to help with severe hair loss.

Deficiency Symptoms: May lead to extreme exhaustion, drowsiness, muscle pain, loss of appetite, depression, grayish skin color. Although a shortage of Biotin is rare, it can happen and may result in dry scaly skin, fatigue, nausea and vomiting, mental depression as well as tongue inflammation and high cholesterol.

Dosage: Recommended dosage for adults 300 microgram (0.3 mg) per day and pregnant and lactating women 300 microgram (0.3 mg) per day. Bodybuilders and athletes consuming raw eggs should be careful of not running into a biotin shortage, since raw eggs contain avidin, which binds with the biotin, making it impossible absorb by the body. Long-term use of antibiotics may also decrease the availability of biotin.

Biotin is present in cheese, beef liver, cauliflower, eggs, mushrooms, chicken breasts, salmon, spinach, brewer's yeast, nuts and can be manufactured in the body should a small shortfall occur.

Toxicity and Symptoms of High Intake: No toxic levels are known, as excesses are easily lost in the urine and feces. No side effects are known.

Vitamin B-12 (Cyanocobalamin)

Helps in the formation and regeneration of red blood cells, thus helping prevent anemia; necessary for carbohydrate, fat and protein metabolism; maintains a healthy nervous system; promotes growth in children; increases energy; needed for calcium absorption.

This complex structured compound with its cobalt cofactor is needed in the body in very small amounts. Vitamin B12 is reportedly needed in the manufacture and maintenance of red blood cells. It reportedly stimulates appetite, promotes growth and release of energy. It is often used with older people to give an energy boost, assist in preventing mental deterioration and helps with thought processes. It may aid with clearing up infections and providing protection against allergies and cancer. This vitamin is also used in the metabolism of fats, proteins and carbohydrates.

Deficiency Symptoms: May lead to pernicious anemia, poor appetite, growth failure in children, tiredness, brain damage, nervousness, neuritis, degeneration of spinal cord, depression, lack of balance. Some symptoms of a deficiency include a sore tongue, weakness, fatigue, and weight loss, back pain and apathy. It may further result in loss of balance, decreased reflexes, tingling of the fingers, ringing in the ears etc. A deficiency may also result in the raising of the level of homocysteine in the blood which in high doses can be toxic to the brain, which may be involved in Alzheimer disease. Severe deficiency may result in pernicious anemia, also called Addisonian pernicious anemia. Another problem that appears in deficiency is the eroding of the myelin sheath—the fatty sheath of tissue, which insulates the nerve fibers.

Dosage: The RDA for males and females is 3 μg per day. People on strict vegetarian and macrobiotic diets are often deficient on Vitamin B12. Some individuals exhibit a deficiency in absorption of vitamin B12 from the intestinal tract, which can lead to pernicious (destructive) anemia. Alcohol consumption or regular use of laxatives or antacids may also result in low B12 levels. Older people may require higher levels of this vitamin as many people older than sixty have difficulty extracting the vitamin from ingested food.

Vitamin B12 is not manufactured by any plants, and is only found in animal products. Therefore, a deficiency may result from strict all-vegetable diets. Unlike other water-soluble vitamins, B12 needs some 3 hours to be absorbed where other B vitamins are absorbed nearly immediately.

Toxicity and Symptoms of High Intake: Toxicity not established but vitamin B12 injections may result in skin problems if in large excess, but will normalize once the injections are stopped.

PABA (Para Amino Benzoic Acid)

Aids beneficial bacteria in producing folic acid; aids in the formation of red blood cells; contains sun screening properties; aids in the assimilation of Pantothenic acid. Para-aminobenzoic acid is often thought of as only an ingredient used in sunscreens, while it is actually also a nutritional ingredient. Since it is a moiety of PGA, a form of folic acid, some health professionals do not consider it a vitamin, but only a B-complex factor.

PABA is used to improve protein use in the body, it assists in red blood cell formation as well as manufacturing folic acid in the intestines. Para-aminobenzoic acid is used in sunscreen preparations since it can help protect the skin against ultra-violet radiation.

People suffering from vitiligo, over-pigmentation of skin, or without pigment in some spots, have reported an improvement of the skin after more PABA was ingested. PABA also assists with breaking down of protein and maintaining intestinal flora.

Deficiency Symptoms: May cause extreme fatigue, eczema, irritability, nervousness, constipation, headaches, digestive disorders, or hair turning prematurely gray. When PABA is in short supply fatigue, irritability, and depression might manifest. Weeping eczema has also been noted in people with PABA deficiency as well as patchy areas on the skin.

Dosage: No recommended dosage but 50 mg per day is usually used in supplementation. Long term antibiotic use may require more PABA from the body, but PABA may interfere with the effectiveness of sulfa drugs.

Toxicity and Symptoms of High Intake: When higher than factor (SPF) 8 sunscreens are used, the manufacture of vitamin D in the body may be reduced. Nausea, skin rashes and vomiting might be indicative of PABA taken in excess. Excessive levels of PABA are stored in the body and may cause liver damage. A ban was placed on the sale of OTC supplements containing large single doses of PABA.

Lecithin

Lecithin contains Choline and Inositol that are reportedly essential for the breakdown of fats and cholesterol. It may prevent arterial congestion, help distribute bodyweight, increase immunity to virus infections, clean the liver and purify the kidneys.

Lecithin is a phospholipid. It is produced daily within the liver if the diet is adequate. It is needed by every cell in the body and largely makes up cell membranes, where it increases membrane fluidity. This makes it ideal in preventing arteriosclerosis and assisting in protecting against cardiovascular disease.

Lecithin protects cells from oxidation, and helps make up the protective sheaths surrounding the brain. Using lecithin can improve brain function and has also been known to promote energy. Lecithin aids in the absorption of thiamine by the liver and is needed to help repair the damage to the liver caused by alcoholism.

Although it is a fatty substance, it is also a fat emulsifier. Lecithin enables fats, such as cholesterol, to be dispersed in water and removed from the body. Hence, it also supports the circulatory system by preventing fatty buildup in the arteries and vital organs.

Oral Application

In preferred embodiments, the disclosed compositions are delivered by oral administration. Oral spray is approximately five times faster and more efficient than capsules, pills or tablets. Intra-oral sprays are one of the fastest ways to deliver any drug, nutrient or vitamin into the bloodstream. There is no waiting for them to take effect. In pill form the body will only process a small fraction of the pill, perhaps as low as 10%. The digestive tract will reduce as much as 90% of the pills effectiveness before it is finally absorbed into the bloodstream. Using intra-oral sprays the nutrients are delivered into the bloodstream very rapidly. In certain embodiments, the disclosed compositions may be delivered to a subject intra-orally using delivery by a spray bottle.

Flavoring

One problem with using an intra-oral spray may be the taste of the composition. In one embodiment, peppermint may be used in sufficient amount to mask the flavor of other components of the composition. In other embodiments, other flavor additives for example fruit flavorings or other mint flavorings may be used. In another embodiment, the flavor of a composition may be one palatable to a mammal other than a human such as a dog or cat. These embodiments by no means limit the flavor options of any of the compositions. In other embodiments, the flavor component may be eliminated if the composition is intended for topical application.

Other than human subjects, other mammals may benefit from the effects of an orally delivered insect inhibiting composition. For example, diseases carried by mosquitoes may also affect dogs, cats, horses or birds etc. In one embodiment, a composition may be applied to a household pet prior to exposure to insects. In another embodiment, a composition may be applied to a dog prior to exposure to a species of flea, tick and/or flying insect (e.g. mosquitoes). In yet another embodiment, a composition may be applied to the oral cavity of a dog, cat, horse or bird. In still another embodiment, a composition may be applied orally and/or externally to a horse for inhibiting mosquitoes or flies (e.g. bottle or deer flies).

A composition comprising one or more of the herbs and vitamins disclosed herein may take many forms. These forms include, a portion, including the entire portion of the amounts recommended for inhibiting biting insects. Suitable forms include but are not limited to liquids and lotions. In addition, the composition may take the form of a portion of a predetermined amount such a quarter or a fifth. For example, a liquid formula may require 4 squirts of the liquid of a quarter strength formula for one individual or five squirts for another individual depending on the age and size of the individual. Alternatively, the composition may be in the form of powder-like consistency that can be hydrated and then used as an insect inhibitor. It is to be appreciated that in these other forms (e.g., paste, time-release formula, tablet etc.), the composition may constitute the entire portion of a predetermined amount of the components or a smaller portion of such predetermined amount.

EXAMPLES

The following are exemplary compositions and/or methods for inhibiting a biting insect. For example, one formula (composition) was tested by several subjects for its ability to inhibit insects (e.g. mosquitoes). In addition, one formula was tested for its ability to relieve inflammation of an insect bite area. These formulas may be used to inhibit a variety of biting insects.

Example 1

Insect Inhibitor Composition and Method

In one exemplary embodiment the following amounts of an insect inhibitor composition were administered in the form of a water-based oral spray, using five squirts from a spray bottle. The indicated amounts are the adult dosage.

Choline (Bitartrate) 150 mg
Inositol 150 mg
B-1 Thiamin (Thiamin Mononitrate) 150 mg
B-2 Riboflavin 150 mg
B-3 Niacin (as Niacinamide) 150 mg
B-5 Panothenic Acid (d-calcium pantothenate) 150 mg
B-6 Pyridoxine (pyridoxine HCL) 150 mg
B-9 Folic Acid 400 mcg
B-12 (as cyanocobalamin) 400 mcg
Biotin (d-biotin) 150 mcg
PABA (Para-Aminobenozoic Acid) 1150 mcg
Barley Grass (*Hordeum vulgare*) 500 mg
Lobelia (stem, leaf, flower) 425 mg
Chlorella 1000 mg
Base mixture: 50 mg
Base:
Watercress 340 mg
Alfalfa (*medicago sativa*) 450 mg
Parsley (leaf) 450 mg
Lecithin 455 mg
Rice Bran 320 mg

In several examples using the above exemplary formula the following doses were applied to prevent insect attack.

Average sized adult: 5 sprays orally
Teen to petite adult: 3 to 4 sprays orally
Child: 2 to 3 sprays orally

Infant:—use externally on exposed skin. Avoid spraying in eyes. If eyes are exposed to the spray, wash with cool, clean water.

In preferred embodiments, the composition is administered daily throughout mosquito season. For maximum protection, it may be administered again 1 to 2 hours before being exposed to mosquitoes.

Example 2

Method of Preparation of One Exemplary Composition

Manufacturing Procedure: For 1,000 fluid finished ounces, 12 gallons of Ionized water were put in a sterile 15 gallon doubled walled, stainless steel kettle. A steam generator was used to generate steam inside the double-walled kettle. The water was steam heated to 180 degrees Fahrenheit.

Using a Ohaus electronic weight scale, the following powdered herbs were weighed and mixed into the heated water:

1 kilogram Peppermint
2 kilograms Barley grass
2 kilograms *Lobelia*
4 kilogram *Chorella*
0.2 kilograms Watercress
0.2 kilograms Alfalfa
0.2 kilograms Parsley
0.2 kilograms Rice bran

The mix was allowed to set at 180 degrees Fahrenheit for 15 minutes. Turning the valve for cold water to flow inside the double-wall, the mixture was cooled to 120 degrees Fahrenheit and stirred with a Helix Double Rotary Mixer every 3 hours for 12 hours.

Turning the valve for cold water to flow inside the double-wall, the mixture was cooled to 80 degrees Fahrenheit. It was then strained three separate times, using stainless steel filters:

1st—a medium filter,
2nd—a fine filter, and
3rd—an extra fine filter.

Preservative: At 80 degrees Fahrenheit, 0.02% in weight (567 mg) Potassium sorbate was added to retard bacterial growth.

Settling: The mixture was allowed to settle to room temperature in a sterile, polyurethane transfer tank for 72 hours. Next, the liquid was siphoned off from the top with a sterile polyurethane hose to a second sterile, polyurethane tank. It was mixed with a blender and the following vitamins were added:

Choline 1 Kilogram
Inositol 1 Kilogram
B-1 Thiamin Mononitrate 1 Kilogram
B-2 Riboflavin 1 Kilogram
B-3 Niacin 1 Kilogram
B-5 Panothenic Acid 1 Kilogram
B-6 Pyridoxine HCL 1 Kilogram
B-9 Folic Acid 12 grams
B-12 Cyanocobalamin 12 grams
d-biotin 5 grams
Para-Aminobenozoic Acid 30 grams
Lecithin 30 grams

The mixture was then mixed with the blender for 5 minutes to produce the final exemplary composition. In one example using a pressurized filling system pump, the liquid of the finished product was bottled. The bottle lids were a mist sprayer with a clear plastic top. Bottles were then labeled and sealed.

Example 3

Administration to Test Subjects

The composition disclosed in Example 2 above was administered as a mosquito inhibitor. Twenty Caucasian adults, 8 males and 12 females, tested the formula over a 2 week period. All reported not being bitten by mosquitoes when they followed directions. When they didn't use the formula and got several bites the subjects administered the formula to the bites prior to going to bed. This topical administration caused the bites to disappear the following day. One subject tested, a Caucasian male of 50, said he did not like the taste and sprayed it on his legs. He said the mosquitoes quit biting him as soon as it was sprayed. Geographic locations of test sites included Texas, Rhode Island, Oregon, Alaska, North Carolina, Florida and Virginia

Example 4

Location: Richmond, R.I. Test area: backyard after a barbeque

Two subjects sprayed the formula in their mouths before they left for the barbeque. As the sun went down the neighbors and fellow guests commented on the number of bites they were receiving. The subjects reported that they hadn't noticed the mosquitoes were particularly bad. Once they got home they checked themselves. Neither subject had been bitten.

Example 5

Location:

Emerald Isle, N.C. (Outer Banks)

Test Area: Home on bog surrounded by marsh areas and brackish waters.

The two subjects ate outdoors in the late evening, just prior to sunset. Upon completing dinner, they each had mosquitoes on their legs. They got several bites. Neither of them had used the composition up to that point in time.

Both subjects sprayed the formula into their mouths and returned outdoors a few minutes later, but received some bites so went back indoors. One subject got 8 to 9 bites that evening—however by the next morning they were all gone. This was not typical for the subject, who reported that without the composition mosquito bites usually lingered for up to a week, with itching and scratching.

After administering the composition again on the next day, the subjects allowed sufficient time for the composition to enter their systems. They reported dramatically improved results for mosquito bites.

Example 6

A subject had been taking daily doses (4 sprays) every morning for about a week. On the night of exposure to insects she added a dose of 4 sprays approximately 2 hours prior to venturing outside. Another subject administered a 7 spray dose approximately 2 hours prior and then a 3 spray dose about 1 hour prior to exposure.

The subjects walked outside and down the stairs of a 75-foot embankment. They could feel mosquitoes and other

insects flying around and near their bodies. They had a flashlight. The mosquitoes were drawn to the light.

They continued to walk 100 yards along the walkway over the marsh areas that led to the pier, stopping periodically to notice if they were being bitten. No bites, but they could feel flying insects around.

They continued at the walkway junction out over the marshes to the end of the pier for another 100 yards or so. They stayed at the end of the pier for about 7 minutes. During that time they held the flashlight out and saw swarms of mosquitoes in the air. Shining the light on their legs and arms they could see mosquitoes land but they did not bite. At least 4–6 mosquitoes landed on each subject.

They retraced their path back to the house. They were exposed for approximately 25 minutes. The second subject did not have any bites at all on his body. The first subject had one mosquito bite on her left foot and a bite behind her left knee that may or may not have been a mosquito. The second subject stayed outdoors for another 20 to 25 minutes; on the front porch, front yard and back porch, still without receiving any bites.

Example 7

Location: Rhode Island, annual block party on a cul-de-sac surrounded by forest and some wetlands, with substantial mosquito exposure.

The two subjects took a five spray dose every three hours. The subjects did not sustain any bites all evening. It was the first time they did not have to bathe in another externally applied offensive insect spray to remain outside and enjoy the party. Other party guests inquired about the product with interest.

Example 8

In one exemplary embodiment the amounts of a recommended dose of an insect inhibitor formula may be in the following range:

about 100 to 425 mg of peppermint;
about 200 to 850 mg of barley grass;
about 200 to 850 mg of *lobelia;*
about 500 to 2000 mg of *chlorella;*
about 20 to 85 mg of watercress;
about 20 to 85 mg of alfalfa;
about 20 to 85 mg of parsley;
about 20 to 85 mg of rice bran;
about 75 to 300 mg of thiamin (B-1);
about 75 to 300 mg of riboflavin (B-2);
about 75 to 300 mg of niacin (B-3);
about 75 to 300 mg of panothenic acid (B-5);
about 75 to 300 mg of pyridoxine (B-6);
about 200 to 800 μg of folic acid (B-9);
about 200 to 800 μg of cyanocobalamin (B-12);
about 75 to 300 mg of choline;
about 75 to 300 mg of inositol;
about 75 to 300 μg of d-biotin;
about 575 to 2300 μg of para-aminobenzoic acid; and
about 575 to 2300 μg of lecithin.

The composition may be used in a variety of applications, such as an oral or topical administration of use to inhibit insects. In another embodiment, one range of the components of the above formula may be used to inhibit mosquitoes. In another embodiment, one range of the components of the above formula may be used as an orally administered insect inhibitor to inhibit mosquitoes and other insects from biting subjects.

Example 9

Two adult subjects, one male and one female, went on a camping trip to Grand Teton National Park in Wyoming. The subjects did not use any topical mosquito repellant. On the first day, subjects each took an oral dose of 5 sprays of the composition disclosed in Example 8, about 30 minutes before walking in a mosquito-infested area of the Park. Subjects suffered a number of mosquito bites, about 20 bites each. Subjects continued to take oral doses of 5 sprays each per day. The subjects noticed that on the second day, they only suffered a few bites each. By the third day, they only suffered one bite each and on the fourth and fifth days of use of the composition they did not notice any mosquito bites, despite returning to the same area where they had received multiple bites the first day. Subjects concluded that the efficacy of the insect inhibitor composition was increased with usage on consecutive days.

Subjects further noticed that on the second day of the camping trip, after having been bitten about 20 times the previous day, they had no symptoms of swelling, redness or itching in the bitten areas. Subjects were very surprised by this, as they expected to have numerous welts and severe itching following that number of mosquito bites. The female subject commented that she always had a severe reaction to mosquito bites, with intense itching, redness and swelling. The female subject was highly allergic to insect toxins and had previously experienced symptoms of incipient anaphylactic shock upon exposure to bee or wasp stings. On subsequent days, subjects noticed that even when they were bitten by mosquitoes, they experienced relatively little itching and no swelling and the insect bites showed no signs of redness, itching or swelling by the day following the bite.

What is claimed is:

1. A composition comprising:
peppermint;
barley grass;
lobelia;
chlorella;
watercress;
alfalfa;
parsley;
rice bran;
thiamin (B-1);
riboflavin (B-2);
niacin (B-3);
pantothenic acid (B-5);
pyridoxine (B-6);
folic acid (B-9);
cyanocobalamin (B-12);
choline;
inositol;
d-biotin;
para-aminobenzoic acid; and
lecithin
wherein said composition inhibits insects from biting a subject after oral administration of the composition to the subject.

2. The composition of claim **1**, wherein said insects are mosquitoes.

3. The composition of claim **1**, wherein said composition inhibits insects from biting when administered as a spray to the oral cavity.

4. The composition of claim **1**, wherein the peppermint, barley grass, *lobelia, chlorella,* watercress, alfalfa, parsley and rice bran are in the form of an extract, concentrate, decoction, infusion, homogenate, essence or distillate.

5. The composition of claim 1, wherein the composition reduces swelling, inflammation and/or itching of the localized area around an insect bite.

6. The composition of claim 5, wherein the composition eliminates swelling, inflammation and/or itching of the localized area around an insect bite within a one day period following the bite.

7. The composition of claim 1, wherein the subject is a human, a dog, a cat or a horse.

8. The composition of claim 1, comprising:
about 100 to 425 mg of peppermint;
about 200 to 850 mg of barley grass;
about 200 to 850 mg of *lobelia;*
about 500 to 2000 mg of *chlorella;*
about 20 to 85 mg of watercress;
about 20 to 85 mg of alfalfa;
about 20 to 85 mg of parsley;
about 20 to 85 mg of rice bran;
about 75 to 300 mg of thiamin (B-1);
about 75 to 300 mg of riboflavin (B-2);
about 75 to 300 mg of niacin (B-3);
about 75 to 300 mg of panothenic acid (B-5);
about 75 to 300 mg of pyridoxine (B-6);
about 200 to 800 μg of folic acid (B-9);
about 200 to 800 μg of cyanocobalamin (B-12);
about 75 to 300 mg of choline;
about 75 to 300 mg of inositol;
about 75 to 300 μg of d-biotin;
about 575 to 2300 μg of para-aminobenzoic acid; and
about 575 to 2300 μg of lecithin.

9. An insect inhibitor kit comprising:
a) a container capable of administering a liquid as a spray; and
b) a liquid form of the composition of claim 1.

* * * * *

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United States Patent [19]

Mantynen

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[54] **METHOD AND COMPOSITION FOR TREATING PSORIASIS**

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[58] **Field of Search** 514/863; 549/408; 426/72

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[57] **ABSTRACT**

This invention pertains to the novel combination of Vitamin E, evening primrose oil and B-complex vitamins as a treatment for patients afflicted with psoriasis. It is postulated that the above compounds act synergistically to provide the cofactors required for normal skin production and repair in psoriatic patients.

11 Claims, No Drawings

METHOD AND COMPOSITION FOR TREATING PSORIASIS

FIELD OF THE INVENTION

This invention pertains to the use of a novel composition comprising Vitamin E, evening primrose oil and B-complex vitamins for treatment of patients afflicted with psoriasis. It is postulated that the above compounds act synergistically to provide the cofactors required for normal skin production in psoriatic patients.

BACKGROUND OF THE INVENTION

The skin is the largest organ in the human body and is in a state of constant turnover. This is accomplished by the outward movement of the basal layer keratinocytes at a rate that varies with age, sex, position on the body and other conditions. Psoriasis, an affliction of the epidermis, is a common disorder present in approximately 6.4 million people in the United States according to the National Psoriasis Foundation. The frequency of the disease varies with race, age, skin location and other conditions. The characteristic feature of psoriasis is hyperproliferation of the keratinocytes, first described by Van Scott and Ekel.[1] There is evidence of significant shortening of the epidermal cell cycle (36 hours versus 311 hours for normal tissue) in the involved skin of patients with psoriasis. In addition there is a doubling of the proliferative cell population and it appears that in psoriatic skin 100% of the germinative cells of the epidermis enter the growth fraction, compared to 60 to 70% for normal skin of non-psoriatic patients. It is felt that as a result of these changes there is an increase in size and in cohesiveness of corneocytes.[2] Transplantation studies of normal and psoriatic human skin to congenitally athymic nude mice have found that, although epidermal proliferation remains above normal in the transplanted psoriatic skin, the absence of clinical lesions (erythema, induration and scaling) suggests that epidermal proliferation does not itself give rise to psoriasis.

The fundamental cellular and metabolic defects underlying psoriasis are not well understood. Endothelial cells, mast cells and fibroblasts have been implicated in the pathogenesis of the disease.[3] Granulocytes are present in the spongioform microabscesses that constitute a hallmark of psoriasis and activation of isolated peripheral granulocytes correlates with disease severity.

Dermal fibroblasts are potent producers of cytokines and lipid mediators that may influence epidermal proliferation as well as the inflammatory reaction seen in psoriasis. Studies of the activity of membrane messenger systems have demonstrated that such systems are activated in psoriatic fibroblasts taken from lesional skin. In these studies the activity of membrane bound but not cytosolic phospholipid/Ca dependent protein kinase C (PKC) was significantly elevated.[4]

Peptide mediators are involved in the inflammatory cascade which takes place in the psoriatic skin. Complement split products, cytokines, interleukins and transforming growth factor alpha are found to be elevated in psoriatic skin.[5] They form part of the body's (defective) skin repair mechanism.

The cyclic nucleotides are not thought to be part of the basic molecular aberration in psoriasis, although it is now agreed that two basic alterations in the second messenger systems occur in psoriatic skin: (1) cyclic GMP levels are elevated in psoriatic lesions, and (2) stimulation of epidermal cells with a beta agonist leads to lower levels of cyclic AMP in the epidermis of lesional skin than in normal or uninvolved skin.[6]

The protease/antiprotease system has also come under scrutiny as increased protease activity has been noted in lesional skin. Proteases have the ability to regulate cell proliferation in other cell systems and can generate inflammatory mediators via the complement cascade.[7]

Utilization of fatty acids by keratinocytes appears to be fundamental to the development of psoriasis and is of relevance to the present invention. In particular, arachidonic acid and linoleic acid are polyunsaturated fatty acids which appear to be destined for different purposes in keratinocytes. Arachidonic acid is metabolized via the cyclooxygenase pathway predominantly into prostaglandins, such as PGE2, PGF2 Alpha, and PGD2, which modulate normal skin physiological processes at low concentrations and inflammatory reactions at high concentrations. Arachidonic acid is also metabolized via the lipoxygenase pathway into 15-hydroxyeicosatetraenoic acid (15-HETE) and other leukotrienes which function as potent inflammatory mediators. These mediators appear to play a role in producing the abnormalities typical of psoriatic lesions, such as infiltration of epidermal cells and epidermal hyperplasia as well as erythema and induration.[8]

The lipoxygenase pathway metabolizes linoleic acid into 13-hydroxy-9, 11-octadecadienoic acid (13-HODE). 13-HODE exerts anti-proliferative properties in keratinocytes, possibly via selective suppression of protein kinase C-beta isozyme activity.[9]

It appears that modulation of the cyclooxygenase and lipoxygenase metabolic pathways may influence psoriasis symptoms. For example, in some patients administration of nonsteroidal antiinflammatory medications (NSAIDS), which are known to inhibit the cyclooxygenase pathway, is associated with the onset or worsening of psoriasis symptoms. It may be that NSAIDS increase the amount of arachidonic acid substrate available to shunt down the lipoxygenase pathway, resulting in increased leukotriene production. By contrast, benoxaprofen, a drug that somewhat selectively blocks the lipoxygenase pathway, has been demonstrated to improve psoriatic symptoms in about 75% of patients studied.

Other findings suggest a possible link between fatty acid metabolism in skin cells and development of psoriasis. Dietary deficiencies of the essential fatty acids linoleic acid and gamma-linoleic acid are associated with increased levels of arachidonic acid and decreased PGE2. Moreover, deficiency of linoleic acid and gamma-linoleic acid has been shown to result in increased DNA synthesis and formation of a scaly dermatosis in some individuals. Also of interest is the finding that human skin fibroblasts preferentially increase linoleic acid incorporation into lipids (80% into phospholipids) and decrease arachidonic acid utilization as they age.[10] This may suggest an increased need for linoleic acid (and a heightened sensitivity to a deficiency thereof) as the fibroblasts age. This finding correlates with the clinical progression of psoriasis. Although psoriasis varies from patient to patient, the overall tendency is for the disease to gradually increase in severity as the patient ages.

Although the exact molecular disruption underlying psoriasis remains elusive, recent studies suggest that psoriasis is an immune-mediated disorder. Early and late onset psoriasis has been associated with certain HLA antigens which may help explain the inheritance pattern of the disease. Activated

T cells are present in abnormally large quantities in active psoriatic skin. T cell derived cytokines are postulated to be candidates for inducing psoriatic changes as IL-2 therapy for malignancy in psoriatic patients has caused severe psoriatic exacerbation. Some therapies which suppress T cell development, such as administration of cyclosporin or psoralen plus Ultraviolet A (PUVA), have proven effective in clearing psoriasis lesions. While such therapies are effective in treating psoriasis, they also affect other cellular systems so the T cell changes may be but one of a number of factors in the pathogenesis of the disease.

Most current treatments for psoriasis act by regulating the immune system or otherwise attenuating the inflammatory response. Internal medications such as cyclosporin, methotrexate and retinoids all have potentially serious side effects such as liver and kidney damage, nausea, birth defects and increased cancer risk. Other common psoriasis treatments are also undesirable for long-term management of the disease. Extended use of topical corticosteroid creams may cause thinning of the skin, stretch marks and suppression of the patient's own cortisol production. Moreover, psoriatic symptoms tend to recur rapidly after cessation of corticosteroid use. Phototherapy can result in skin aging and increased risk of skin cancer.

The need has therefore arisen for a non-toxic, long-term treatment for psoriasis which does not merely attenuate inflammatory symptoms but endeavours to remedy local cellular nutritional deficiencies underlying the disease.

SUMMARY OF THE INVENTION

The invention relates to the use of a specific combination of Vitamin E, evening primrose oil and B-complex vitamins for treatment of psoriasis. It is postulated that the above compounds act synergistically to provide the cofactors required for normal skin production and repair in psoriatic patients. When administered alone, the compounds do not produce significant improvement in psoriasis, but when administered together orally they can significantly decrease the severity and extent of psoriasis present in afflicted patients. The compounds are non-toxic as compared to other oral medications available for the treatment of psoriasis, all which have significant adverse effects.

In accordance with the invention a method for treating psoriasis in a human patient is disclosed comprising administering to the patient on a continuing basis therapeutic amounts of Vitamin E, evening primrose oil and B-complex vitamins in combination. The B-complex vitamins preferably comprise folic acid and lipotropic factors, such as choline bitartrate and inositol. Preferably, the above compounds are administered daily by oral ingestion. The preferred daily dosages are within the following ranges:

Vitamin E: 400–1600 IU/day.

Evening primrose oil: 1–6 grams.

B-complex vitamins: 50–200 micrograms. (excluding folic acid)

Folic acid: 0.4–1.6 milligrams

More particularly, the method comprises administering to the patient on a daily basis therapeutic amounts in combination of (a) Vitamin E; (b) fatty acids selected from the group consisting of linoleic acid and gamma linoleic acid; and (c) B-complex vitamins selected from the group consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, Vitamin B-5, Vitamin B-6, Vitamin B-12, biotin, folic acid, para amino benzoic acid and lipotropic factors. Compositions for the treatment of psoriasis are also provided comprising combinations of the above compounds.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Definitions

As used herein the following terms shall have the following respective meanings:

"evening primrose oil" means oil extracted from evening primrose seeds and comprising linoleic acid and gamma-linoleic acid.

"Vitamin E" means d-alpha tocopherol.

"B-complex vitamins" means vitamins selected from the group consisting of Vitamin B-1 (thiamine hydrochloride), Vitamin B-2 (riboflavin), Vitamin B-3 (niacinamide), Vitamin B-5 (pantothenic acid or calcium pantothenate), Vitamin B-6 (pyridoxine hydrochloride), Vitamin B-12 (cyanocobalamine), biotin, folic acid, para amino benzoic acid and lipotropic factors.

"Lipotropic Factors" means factors which support lipid metabolism selected from the group consisting of choline bitartrate and inositol.

Description

This invention relates to a method and composition for treating psoriasis comprising the use in combination of Vitamin E, evening primrose oil and B-complex vitamins. It is postulated that the above compounds act synergistically to provide the cofactors required for normal skin production in psoriasis patients.

Psoriatic skin turns over at an extremely rapid rate (approximately every four days as compared to twenty-eight days for normal skin). This results in a corresponding increase in demand for various metabolic substrates necessary for skin production. Although the precise metabolic defects underlying psoriasis remain unknown, the inventor has identified the essential fatty acid linoleic acid as one important metabolic substrate which may be deficient in psoriasis patients.

Keratinocytes utilize both linoleic acid and arachidonic acid. As discussed above, linoleic acid deficiencies may result in increased utilization of arachidonic acid in afflicted individuals via the lipoxygenase pathway, resulting in the production of inflammatory mediators such as leukotrienes which have been implicated in psoriasis pathogenesis. This effect is worsened by an increased amount of psoriasis and a corresponding increased rate of cell turnover. As the psoriatic lesions spread over a wider surface area of the patient's body, local cellular deficiencies of metabolic substrates such as linoleic acid will be exacerbated, resulting in a still greater likelihood that additional lesions will develop.

Apart from linoleic acid, various other metabolic substrates and cofactors undoubtedly play a role in skin cell production and repair in psoriasis patients. Vitamin E is postulated to have synergistic effect when added to linoleic acid and gamma-linoleic acid by inhibiting their peroxidation and by stabilizing the cell membrane.[11] Deficiencies in various of the B-complex vitamins have also associated with skin tissue disorders. Biotin, Vitamin B-1, and B-3 deficiencies produce scaling dermatoses. Vitamin B-5 is important in fatty acid synthesis. Vitamin B-6 is required for the desaturation and elongation of linoleic acid and may in such fashion influence prostaglandin production.

Folic acid, which is also a member of the B-complex family, is a necessary factor in skin replication. The drug methotrexate reduces hyperproliferation of the epidermis in psoriasis by inhibiting folic acid utilization. Serum folic acid deficiency is well documented in patients with longstanding psoriasis and may be in large measure contribute to their increased risk of vascular occlusive disease (due to increased homocysteine production).

The lipotropic factors choline bitartrate and inositol are necessary substrates for the formation of phospholipids that carry the monohydroxy fatty acids that may influence signal transduction and eicosanoid metabolism in psoriatic keratinocytes.

The inventor has postulated that the availability of fatty acids (such as linoleic acid and gamma-linoleic acid), Vitamin E, and various B-complex vitamins (including folic acid and lipotropic factors), may be insufficient in psoriasis patients due to rapid cell cycling. As set forth in the following case histories, it has been determined that oral supplementation of a combination of the above compounds results in a marked reduction in psoriasis symptoms, including psoriatic nail disease, in some afflicted individuals.

Case Histories

EXAMPLE 1

AB, a 50 year old female, had been suffering from chronic severe psoriasis for 31 years (since age 19). Over the years AB had tried various psoriasis treatments including topical and injected corticosteroids, coal tars, phototherapy, photochemotherapy (PUVA) and methotrexate. None of these treatments provided long-term relief from psoriasis symptoms. Following methotrexate treatment in 1990, AB was free from psoriasis symptoms for approximately six months. Symptoms then recurred and higher doses of methotrexate were prescribed which resulted in unacceptable side effects.

AB was administered the composition of the present invention for a trial period in the following daily dosages:

1. 800 I/U Vitamin E in a gelatin capsule
2. 1000 mg evening primrose oil in a gelatin capsule; and
3. B-complex vitamins, namely 100 mcg each of B-1, B-2, B-3, B-5, B-6, B-12, biotin, choline bitartrate; and 800 mcg folic acid.

At the commencement of treatment AB's psoriasis had flared and the symptoms were severe. Virtually AB's entire body was covered in psoriatic lesions except for her face. AB could not walk or bend her arms without severe discomfort. Within two weeks from the commencement of treatment AB noticed that the psoriatic lesions on her hands were healing. Within one month all of the psoriatic lesions on AB's upper body had cleared. At the end of a six week trial period AB was substantially free from psoriatic lesions, apart from some relatively small patches on her legs. The psoariatic lesions had largely been replaced with new skin tissue which was normal in appearance and pigmentation.

AB was then given a placebo drug combination in the following daily dosages:

1. 25,000 I/U Beta-carotene
2. 1000 mg Vitamin C
3. 2 capsules lactobacillus commensals (sold by Holista Health Foods under the trademark INTESTALIFE)

After approximately two weeks of placebo administration, AB's psoriasis symptoms began to recur. At the end of a six week trial period lesions had reappeared on her legs, hips and under her breasts.

EXAMPLE 2

CD, a 41 year old male, had been suffering from chronic, moderately severe psoriasis since age 12. Over the years CD had tried various psoriasis treatments including coal tars, topical steroidal creams, anthralin, calcipotriol and Ultraviolet B (UVB) light therapy. None of these treatments provided long-term relief from psoriasis symptoms. CD also had moderately severe psoriatic nail disease (onycholysis) which was unresponsive to treatment.

CD was administered oral supplements comprising the composition of the present invention for a trial period in the following typical daily dosages:

1. 800 I/U Vitamin E in a gelatin capsule
2. 2–3 g evening primrose oil in a gelatin capsule; and
3. B complex vitamins, namely 100 mcg each of B-1, B-2, B-3, B-5, B-6, B-12, biotin, choline bitartrate; and **800** mcg folic acid

During the trial period CD experienced a 90% reduction in the severity of his psoriasis and his psoriatic nail disease symptoms cleared entirely. At one point during the trial period CD ceased taking the test composition for a period of two months. During this hiatus in treatment CD experienced a dramatic worsening of his psoriasis skin condition. When CD resumed the active drug treatment of the present invention following the two month hiatus, his skin condition once again improved markedly. The 90% reduction in the severity of psoriasis symptoms experienced by CD during the trial period has been maintained and tachyphylaxis has not occurred at the dosages set forth above.

EXAMPLE 3

EF, a 52 year old male, with a history of moderately severe psoriasis of 40 years duration was treated with oral supplements comprising the composition of the present invention. Previous treatments had no sustained benefit and included Goeckermann regimes (coal tar and UVB phototherapy), steroids and calcipotriol. The oral supplements of the present invention were administered for a trial period in the following daily dosages:

1. 800 I/U Vitamin E in a gelatin capsule
2. 3 g evening primrose oil in a gelatin capsule; and
3. B complex vitamins, namely 100 mcg each of B-1, B-3, B-5, B-6, B-12, biotin, choline bitartrate; and 800 mcg folic acid

At the commencement of treatment date EF weighed approximately 100 kg and had approximately 25% skin surface area involvement with thick plaque psoriasis. During a two month trial period the plaque psoriasis lesions faded to flat pink patches. This clinical improvement has been sustained.

Summary

The use of evening primrose oil in combination with Vitamin E and B-complex vitamins (including folic acid and lipotropic factors choline bitartrate and inositol) has been shown to be a valuable adjunctive treatment in the management of psoriasis and indeed in some cases may obviate the need for other treatments to maintain normal appearing skin. The fact that these compounds may be administered orally as dietary supplements and are non-toxic in the appropriate prescribed doses makes this treatment approach especially appealing.

As should be apparent to someone skilled in the art, the preferred dosages of the active compounds of the invention are dependent on the size of the patient and the extent of skin surface area involvement. For example, very large patients with extensive psoriatic lesions have higher metabolic demands and consequently require higher dosages of the active compounds of the invention in order to achieve optimum results.

As will be apparent to those skilled in the art in the light of the foregoing disclosure, many alterations and modifications are possible in the practice of this invention without departing from the spirit of the scope thereof. Accordingly, the scope of the invention is to be construed in accordance with the combination of substances defined by the following claims.

REFERENCES

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What is claimed is:

1. A method for treating psoriasis in a human patient comprising administering to said patient by oral ingestion on a continuing basis therapeutic amounts in combination of Vitamin E, evening primrose oil, folic acid and B-complex vitamins selected from the group consisting of Vitamin B-1, Vitamin B-2 Vitamin 3, Vitamin B-6, Vitamin B-12, biotin, para amino benzoic acid and lipotropic factors.

2. The method of claim **1**, wherein said therapeutic amounts are administered daily.

3. The method of claim **1**, wherein the daily dosage of said Vitamin E is within the range of 400–1600 IU.

4. The method of claim **3**, wherein the daily dosage of said evening primrose oil is within the range of 1–6 grams.

5. The method of claim **4**, wherein the daily dosage of each of said B-complex vitamins is within the range of 50–200 micro grams.

6. The method of claim **5**, wherein the daily dosage of said folic acid is within the range of 0.4–1.6 milligrams.

7. A method for treating psoriasis in a human being patient comprising administering to said patient on a daily basis therapeutic amounts in combination of (a) Vitamin E; (b) fatty acids selected from the group consisting of linoleic acid and gamma inoleic acid; (c) folic acid and (d) B-complex vitamins selected from the group consisting of consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, Vitamin B-5, Vitamin B-6, Vitamin B-12, biotin, para amino benzoic acid and lipotropic factors.

8. A composition for the treatment of psoriasis comprising in combination a pharmaceutical carrier suitable for oral administration and a therapeutically effective amount of:

(a) Vitamin E;

(b) evening primrose oil;

(c) folic acid; and

(d) B-complex vitamins selected from the group consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, Vitamin B-5, Vitamin B-6, Vitamin B-12, biotin, para amino benzoic acid and lipotropic factors.

9. A composition for the treatment of psoriasis comprising in combination a pharmaceutical carrier suitable for oral administration and a therapeutically effective amount of:

(a) Vitamin E;

(b) fatty acids selected from the group consisting of linoleic acid and gamma-linoleic acid;

(c) folic acid; and

(d) B complex vitamins selected from the group consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, Vitamin B-5, Vitamin B-6, Vitamin B-12, biotin, para amino benzoic acid and lipotropic factors.

10. A dietary supplement to be ingested orally for treatment of psoriasis comprising a pharmaceutical carrier suitable for oral administration and a therapeutically effective amount of:

(a) Vitamin E;

(b) evening primrose oil;

(c) folic acid; and

(d) B complex vitamins selected from the group consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, Vitamin B-5, Vitamin B-6, Vitamin B-12, biotin, para amino benzoic acid and lipotropic factors.

11. A method for treating psoriasis in a human patient comprising administering to said patient by oral ingestion on a continuing basis therapeutic amounts of Vitamin E; essential fatty acids selected from the group consisting of linoleic acid and gamma linoleic acid; folic acid; and B-complex vitamins selected from the group consisting of consisting of Vitamin B-1, Vitamin B-2, Vitamin B-3, B-5, Vitamin B-6, Vitamin b-12, biotin, para amino acid and lipotropic factors.

* * * * *

Claims

1. (Previously presented) A method of treating psoriasis by administering to a person a vitamin supplement composition comprising at least about 25 micrograms to about 2,200 micrograms of folic acid, at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}, and at least about 0.5 milligrams to about 20 milligrams of vitamin B_6, wherein said composition is essentially free of anti-oxidants.

Claims 2-7 (Canceled).

8. (Previously presented) The method of claim 1 wherein said composition is in the form of a tablet.

9. (Previously presented) The method of claim 1 wherein said composition comprises 800 micrograms of folic acid, 115 micrograms of vitamin B_{12}, and 10 milligrams of vitamin B_6.

10. (Original) The method of claim 9 wherein said composition is in the form of a tablet.

11. (Previously presented) A method of treating dandruff by administering to a person a vitamin supplement composition consisting essentially of folic acid and vitamin B_{12}, wherein said composition is essentially free of anti-oxidants.

Claims 12-13 (Canceled).

14. (Previously presented) The method of claim 11 wherein said composition contains at least about 25 micrograms to about 2,200 micrograms of folic acid and at least about 25 micrograms to about 2,500 micrograms of vitamin B_{12}.

Claims 15-24 (Canceled).

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 5th day of July, 2013, I caused this Corrected Joint Appendix to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

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Upon acceptance by the Clerk of the Court of the electronically filed document, the required number of copies of the Corrected Joint Appendix will be hand filed at the Office of the Clerk, United States Court of Appeals for the Federal Circuit in accordance with the Federal Circuit Rules.

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